

Medicare Program Integrity Manual

Chapter 4 - Benefit Integrity

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4.1 - Introduction

(Rev. 71, 04-09-04)

The Program Integrity Manual (PIM) reflects the principles, values, and priorities of the Medicare Integrity Program (MIP). The primary principle of Program Integrity (PI) is to pay claims correctly. In order to meet this goal, Program Safeguard Contractors (PSCs), Affiliated Contractors (ACs), and Medicare contractors must ensure that they pay the right amount for covered and correctly coded services rendered to eligible beneficiaries by legitimate providers. The Centers for Medicare & Medicaid Services (CMS) follows four parallel strategies in meeting this goal: 1) preventing fraud through effective enrollment and through education of providers and beneficiaries, 2) early detection through, for example, medical review and data analysis, 3) close coordination with partners, including PSCs, ACs, Medicare contractors, and law enforcement agencies, and 4) fair and firm enforcement policies.

Fiscal Intermediaries (FIs) and Carriers that have transitioned their Benefit Integrity (BI) work to a PSC (referred to as Affiliated Contractors or ACs) and Fiscal Intermediaries and Carriers that have not transitioned their BI work to a PSC (from this point forward, referred to as Medicare contractors) shall follow the entire PIM for BI functions as they relate to their respective roles and areas of responsibility relating to BI.

The ACs and DMERCs shall use the PSC support service activity codes in the Budget Performance Requirements (BPR) to report costs associated with support services provided to the PSC.

The PSCs shall follow the PIM to the extent outlined in their respective task orders. The PSC shall only perform the functions outlined in the PIM as they pertain to their own operation. The PSC, in partnership with CMS, shall be proactive and innovative in finding ways to enhance the performance of PIM guidelines.

4.1.1 - Definitions

(Rev. 71, 04-09-04)

To facilitate understanding, the terms used in the PIM are defined in PIM Exhibit 1.

4.2 - The Medicare Fraud Program

(Rev. 144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

The primary goal of the PSC and the Medicare contractor BI unit is to identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are recouped. Suspension and denial of payments and the recoupment of overpayments are an example of the actions that may be taken. All cases of potential fraud are referred to the Office of Inspector General (OIG), Office of Investigations field office (OIFO) for consideration and initiation of criminal or civil prosecution, civil monetary penalty, or administrative sanction actions. AC and Medicare

contractor personnel conducting each segment of claims adjudication, Medical Review (MR), and professional relations functions shall be aware of their responsibility for identifying fraud and be familiar with internal procedures for forwarding potential fraud cases to the PSC and the Medicare contractor BI unit. Any area within the AC (e.g., medical review, enrollment, second level screening staff) that refers potential fraud and abuse to the PSC shall maintain a log of all these referrals, and all areas within the Medicare contractor shall maintain a log of all potential fraud and abuse referrals to the Medicare contractor BI unit. At a minimum, the log shall include the following information:

provider/physician/supplier name, beneficiary name, HIC number, nature of the referral, date the referral is forwarded to the PSC or Medicare contractor BI unit, name and contact information of the individual who made the referral, and the name of the PSC or Medicare contractor BI unit *to whom the referral was made*.

Preventing and detecting potential fraud involves a cooperative effort among beneficiaries, PSCs, ACs, Medicare contractors, providers, quality improvement organizations (QIOs), state Medicaid fraud control units (MFCUs), and Federal agencies such as CMS, the Department of Health and Human Services (DHHS), OIG, the Federal Bureau of Investigation (FBI), and the Department of Justice (DOJ).

Each investigation is unique and shall be tailored to the specific circumstances. These guidelines are not to be interpreted as requiring the PSCs and Medicare contractor BI units to follow a specific course of action or establishing any specific requirements on the part of the government or its agents with respect to any investigation. Similarly, these guidelines shall not be interpreted as creating any rights in favor of any person, including the subject of an investigation.

When the PSC or Medicare contractor BI unit has determined that a situation is not fraud, it shall refer these situations to the appropriate unit at the PSC, AC, or Medicare contractor.

4.2.1 - Examples of Medicare Fraud **(Rev. 71, 04-09-04)**

The most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program. The violator may be a provider, a beneficiary, or an employee of a provider or some other person or business entity, including a billing service or an intermediary employee.

Providers have an obligation, under law, to conform to the requirements of the Medicare program. Fraud committed against the program may be prosecuted under various provisions of the United States Code and could result in the imposition of restitution, fines, and, in some instances, imprisonment. In addition, there is also a range of administrative sanctions (such as exclusion from participation in the program) and civil

monetary penalties that may be imposed when facts and circumstances warrant such action.

Fraud may take such forms as:

- Incorrect reporting of diagnoses or procedures to maximize payments.
- Billing for services not furnished and/or supplies not provided. This includes billing Medicare for appointments that the patient failed to keep.
- Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both Medicare and the beneficiary for the same service, or billing both Medicare and another insurer in an attempt to get paid twice.
- Altering claim forms, electronic claim records, medical documentation, etc., to obtain a higher payment amount.
- Soliciting, offering, or receiving a kickback, bribe, or rebate, e.g., paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment.
- Unbundling or “exploding” charges.
- Completing Certificates of Medical Necessity (CMNs) for patients not personally and professionally known by the provider.
- Participating in schemes that involve collusion between a provider and a beneficiary, or between a supplier and a provider, and result in higher costs or charges to the Medicare program.
- Participating in schemes that involve collusion between a provider and an AC or Medicare contractor employee where the claim is assigned, e.g., the provider deliberately over bills for services, and the AC or Medicare contractor employee then generates adjustments with little or no awareness on the part of the beneficiary.
- Billing based on “gang visits,” e.g., a physician visits a nursing home and bills for 20 nursing home visits without furnishing any specific service to individual patients.
- Misrepresentations of dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services.
- Billing non-covered or non-chargeable services as covered items.

- Repeatedly violating the participation agreement, assignment agreement, and the limitation amount.
- Using another person's Medicare card to obtain medical care.
- Giving false information about provider ownership in a clinical laboratory.
- Using the adjustment payment process to generate fraudulent payments.

Examples of cost report fraud include:

- Incorrectly apportioning costs on cost reports.
- Including costs of non-covered services, supplies, or equipment in allowable costs.
- Arrangements by providers with employees, independent contractors, suppliers, and others that appear to be designed primarily to overcharge the program through various devices (commissions, fee splitting) to siphon off or conceal illegal profits.
- Billing Medicare for costs not incurred or which were attributable to non-program activities, other enterprises, or personal expenses.
- Repeatedly including unallowable cost items on a provider's cost report except for purposes of establishing a basis for appeal.
- Manipulation of statistics to obtain additional payment, such as increasing the square footage in the outpatient areas to maximize payment.
- Claiming bad debts without first genuinely attempting to collect payment.
- Certain hospital-based physician arrangements, and amounts also improperly paid to physicians.
- Amounts paid to owners or administrators that have been determined to be excessive in prior cost report settlements.
- Days that have been improperly reported and would result in an overpayment if not adjusted.
- Depreciation for assets that have been fully depreciated or sold.
- Depreciation methods not approved by Medicare.
- Interest expense for loans that have been repaid for an offset of interest income against the interest expense.

- Program data where provider program amounts cannot be supported.
- Improper allocation of costs to related organizations that have been determined to be improper.
- Accounting manipulations.

4.2.2 - Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The PSC and Medicare contractor BI unit is responsible for preventing, detecting, and deterring Medicare fraud. The PSC and Medicare contractor BI unit:

- Prevents fraud by identifying program vulnerabilities.
- Proactively identifies incidents of potential fraud that exist within its service area and takes appropriate action on each case.
- Investigates (determines the factual basis of) allegations of fraud made by beneficiaries, providers, CMS, OIG, and other sources.
- Explores all available sources of fraud leads in its jurisdiction, including the MFCU and its corporate anti-fraud unit.
- Initiates appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud.
- Refers cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions (see PIM, chapter 4, §§4.18ff, 4.19ff, and 4.20ff).
- Provides outreach to providers and beneficiaries.

Initiates and maintains networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups.

The PSCs and Medicare contractor BI units are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices.

Proactive (self-initiated) leads may be generated and/or identified by any internal PSC, AC, or Medicare contractor component, not just the PSC and Medicare contractor BI units (e.g., claims processing, data analysis, audit and reimbursement, appeals, medical review, enrollment). However, the PSCs and Medicare contractor BI units shall pursue leads through data analysis (PSCs shall follow chapter 2, §2.3 for sources of data), the Internet, the fraud investigation database (FID), news media, etc.

The PSCs and Medicare contractor BI units shall take prompt action after scrutinizing billing practices, patterns, or trends that may indicate fraudulent billing, i.e., reviewing data for inexplicable aberrancies (other than the expected) and relating the aberrancies to specific providers, identifying “hit and run” providers, etc. PSCs and Medicare contractor BI units shall meet periodically with staff from their respective internal components and PSCs shall also meet with AC staff to discuss any problems identified that may be a sign of potential fraud.

Fraud leads from any external source (e.g., law enforcement, CMS referrals, beneficiary complaints) are considered to be reactive and not proactive. However, taking ideas from external sources, such as non-restricted fraud alerts and using them to look for unidentified aberrancies within PSC or Medicare contractor data is proactive.

4.2.2.1 - Organizational Requirements

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Organizationally, each Medicare contractor that has not transitioned to a PSC shall have a component responsible for the detection, development, and initiating corrective action of fraud cases. Staff supervised by a full-time unit manager shall conduct required fraud activities. This group is referred to as the Benefit Integrity unit. It may consist of employees who work full-time on Medicare fraud issues or employees who work part-time on Medicare and part-time on BI or fraud for the Medicare contractor's private line of business. If an employee works on both Medicare and private-side cases, the Medicare contractor shall not mix Medicare and private-side data. Staff from the BI unit shall identify themselves to providers with their name and the name of the PSC or Medicare contractor when making contact with providers suspected of committing fraud. If workload supports a full-time unit, it shall be a separate and distinct unit within the Medicare contractor organization and may not be combined with the MR and corporate-side PI units, i.e., it shall handle only Medicare cases. Multi-state Medicare contractors shall maintain at least one contact at each site. Separate time records shall be maintained on any part-time staff assigned to the BI unit. Large Medicare contractors shall, however, establish separate distinct BI units. Regardless of the number of personnel in the BI unit, all necessary action shall be taken to ensure the integrity of Medicare payments. This means that an effective Medicare payment safeguard program shall be in place.

Full PSCs are not required to separate their MR and BI units. However, all BI information shall be kept confidential and secure and shared with MR only on a need-to-know basis.

The PSC and Medicare contractor BI unit managers **shall** have sufficient authority to guide BI activities. The managers **shall** be able to establish, control, evaluate, and revise fraud-detection procedures to ensure their compliance with Medicare requirements.

The PSC and Medicare contractor BI unit manager shall prioritize work coming into the PSC or Medicare contractor BI unit to ensure that investigations and cases with the

greatest program impact/and or urgency are given the highest priority. Allegations or cases having the greatest program impact would include cases involving:

- Patient abuse or harm.
- Multi-state fraud.
- High dollar amounts of potential overpayment.
- Likelihood for an increase in the amount of fraud or enlargement of a pattern.
- Fraud complaints made by Medicare supplemental insurers. PSCs, ACs, and Medicare contractors shall give high priority to fraud complaints made by Medicare supplemental insurers. If a referral by a Medigap insurer includes investigatory findings indicating fraud stemming from site reviews, beneficiary interviews and/or medical record reviews, PSCs and Medicare contractor BI units shall 1) conduct an immediate data run to determine possible Medicare losses, and 2) refer the case to the OIG.
- Law enforcement requests for assistance that involve responding to court-imposed deadlines.
- Law enforcement requests for assistance in ongoing investigations that involve national interagency (DHHS -DOJ) initiatives or projects.

4.2.2.2 - Liability of Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit Employees (Rev. 71, 04-09-04)

Under the terms of their contracts and proposed rule 42 CFR § 421.316(a), PSCs, their employees and professional consultants are protected from criminal or civil liability as a result of the activities they perform under their contracts as long as they use due care. If a PSC, or any of its employees or consultants are named as defendants in a lawsuit, CMS will determine, on a case-by-case basis, whether to request that the U.S. Attorney's office offer legal representation. If the U.S. Attorney's office does not provide legal representation, the PSC will be reimbursed for the reasonable cost of legal expenses it incurs in connection with defense of the lawsuit as long as funds are available and the expenses are otherwise allowable under the terms of the contract.

When a provider is under investigation, the provider might sue the Medicare contractor BI unit. Such suits are not common, and even more rarely are they successful. It should be noted that courts, over the past several years, have begun sanctioning attorneys for filing frivolous complaints. Courts have generally agreed that as agents of the federal government, Medicare contractor BI units have what is referred to as official immunity.

The doctrine of official immunity provides that government officials enjoy an absolute privilege from civil liability should the activity in question fall within the scope of their authority and if the action undertaken requires the exercise of discretion. Moreover, Medicare contractors are assured an offer of a defense by the U.S. Attorney's office as long as the Medicare contractors were performing activities required by CMS and were within the scope of the job description. Medicare contractors are protected even if the Medicare contractors make honest mistakes or errors of judgment.

Medicare contractors are not protected if the Medicare contractors go beyond their authority or scope of activities or commit torts or criminal acts (e.g., libel or trespass). Medicare contractors are subject to risk if the Medicare contractors act with malice or vindictiveness.

Investigating fraud and prosecuting offenders falls well within the government's interests and whatever resources are needed will be used to protect Medicare contractors and those activities. Sections 1816(i) and 1842(e) of the Social Security Act (the Act) are the authorities that CMS has construed to provide a basis for Medicare contractors' entitlement to indemnification for litigation costs and adverse judgments that are incurred as a consequence of performing the claims payment portion of their official duties. This includes fraud and abuse activities.

When Medicare contractor BI units are served with a complaint, they shall immediately contact the corporate general counsel. If a PSC is served with a complaint, it shall immediately contact its chief legal counsel and GTL. PSCs and Medicare contractor BI units shall forward the complaint to the Department of Health and Human Services Office of the regional chief counsel (CMS regional attorney) who, in turn, will notify the U.S. Attorney. The HHS office forwards complaints against Medicare contractor BI units to the U.S. Attorney within 20 calendar days of receipt. The HHS office and/or the GTL will notify the PSC whether legal representation will be sought from the U.S. Attorney prior to the deadline for filing an answer to the complaint.

4.2.2.3 – Anti-Fraud Training (Rev. 71, 04-09-04)

All levels of PSCs and Medicare contractor employees shall know the goals and techniques of fraud detection and control in general and as they relate to their own areas of responsibility (i.e., general orientation for new employees and highly technical sessions for BI unit, claims processing, medical review, audit, and appeals staff). All PSCs and Medicare contractor BI unit staff shall be adequately qualified for the work of detecting and investigating situations of potential fraud. CMS separates the requirements into two different levels in recognition that new and experienced staff have different needs. Medicare contractor BI units shall consult the Regional Office (RO) if they want to confirm that specific training sessions will meet CMS's requirements.

A. Level I - One-Time Completion

This does not apply to PSCs.

Within the first year of employment, Medicare contractor BI unit employees shall complete 36 hours of Level I training, as per the three categories below. This training will be directly pertinent to fraud detection and investigation and easily applied to the health care and Medicare environment. This means that Level I training shall be completed one-time only.

- Fraud detection - 16 hours
- Data analysis - 16 hours
- Interviewing techniques - 4 hours

B. Level II - Annual Completion

This does not apply to PSCs.

Medicare contractor BI unit employees shall annually complete a total of 6 hours of advanced training, to maintain skills and learn the most advanced techniques in 2 areas that can be easily applied to the health care and Medicare environment:

- Advanced fraud detection - 4 hours
- Advanced data analysis - 2 hours

C. CMS National Benefit Integrity Training

Each PSC and Medicare contractor BI unit shall send the appropriate representative(s) to CMS's national benefit integrity training each year it is provided.

4.2.2.3.1 - Training for Law Enforcement Organizations (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The FBI agents and DOJ attorneys need to understand Medicare. PSCs and Medicare contractors BI units shall conduct special training programs for them upon request. PSCs and Medicare contractors should also consider inviting appropriate DOJ, OIG, and FBI personnel to existing programs intended to orient employees to PSC or Medicare contractor operations, or to get briefings on specific cases or Medicare issues.

4.2.2.4 - Procedural Requirements (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Contractors shall provide written procedures for Medicare contractor BI unit personnel and for personnel in other Medicare contractor components (claims processing, MR,

beneficiary services, intermediary audit, etc.) to help identify potential fraud situations. Include provisions to ensure that personnel shall:

- Refer potential fraud cases promptly to the BI unit.
- Forward complaints alleging fraud through the second level screening staff to the BI unit.
- Maintain confidentiality of referrals to the BI unit so that the civil rights of those involved are protected.
- Forward to the BI unit documentation of the details of telephone or personal contacts involving fraud issues discussed with providers or provider staff, and retain such information in individual provider files.

In addition, PSCs and Medicare contractor BI units shall ensure the performance of the functions below and have written procedures for these functions:

- Keep educational/warning correspondence with providers and other fraud documentation concerning specific issues in individual provider files (refer to §4.2.2.4.2 for retention of this documentation), so that PSCs and Medicare contractors are able to retrieve such documentation easily.
- Maintain communication and information flowing between the PSC or Medicare contractor BI unit, and the PSC, AC, or Medicare contractor MR staff, and as appropriate, intermediary audit staffs.
- Communicate with the AC or Medicare contractor medical review staff on all findings of overutilization and coordinate with the AC or Medicare contractor medical review staff to determine what, if any, education has been provided before any BI investigation is pursued.
- Obtain and share information on health care fraud issues/fraud investigations among carriers (including durable medical equipment regional carriers (DMERCs)), fiscal intermediaries (including rural home health intermediaries (RHHIs)), PSCs, CMS, and law enforcement.
- Serve as a reference point for law enforcement and other organizations and agencies to contact when they need help or information on Medicare fraud issues and do not know whom to contact.
- Coordinate and attend fraud-related meetings/conferences and inform all appropriate parties about these meetings/conferences. These meetings/conferences include, but are not limited to, health care task force meetings and conference calls.

- Distribute fraud alerts to the appropriate parties. Share PSC and Medicare contractor BI unit findings on fraud alerts with PSCs and Medicare contractors within the appropriate jurisdiction and CMS.
- Work with the Primary GTL, Associate GTL, and SME (if a PSC) and CMS RO (if a Medicare contractor) to develop and organize external programs and perform training as appropriate for law enforcement, ombudsmen, grantees (e.g., Harkin Grantees or Senior Medicare Patrol) and other CMS health care partners (e.g., AoA, state MFCU).
- Serve as a resource to CMS as necessary. For example, serve as a resource to CMS on the FID, including FID training.
- Help to develop fraud-related outreach materials (e.g., pamphlets, brochures, videos) in cooperation with beneficiary services and/or provider relations departments of the ACs and Medicare contractors, for use in their training. Submit written outreach material to the CMS RO (if a Medicare contractor) and the Primary GTL, Associate GTL, and SME (if a PSC) for clearance.
- Assist in preparation and development of fraud-related articles for AC and Medicare contractor newsletters/bulletins. The PSC and Medicare contractor BI unit shall send CMS CO a copy of these newsletters/bulletins to the following address:

Centers for Medicare & Medicaid Services (CMS)
 Re: Newsletter/Bulletin Articles
 Division of Benefit Integrity Management Operations
 Mail Stop C3-02-16
 7500 Security Boulevard
 Baltimore, Maryland 21244

- Provide resources and training for the development of internal and new hire fraud training.
- Take appropriate administrative action on cases not accepted by OIG or other investigative agencies. At a minimum, provide information for recovery of identified overpayments and other corrective actions discussed in PIM, chapter 3, §§8ff and 9ff.
- Subject to the requirements in PIM, chapter 4, §4.4.1, provide support to law enforcement agencies for investigation of potential fraud and abuse, including investigations for which an initial referral to law enforcement did not originate from the PSC or Medicare contractor BI unit.
- Properly prepare and document cases referred to OIG/OI; two copies of a summary report of investigation shall be included with each fraud referral made to

the OIG. The referral format listed in PIM Exhibits 16.1 and 16.2 shall be followed, unless written guidance is provided by the applicable OIG/OI office and approved by the Primary GTL, Associate GTL, and SME (if a PSC) or the applicable CMS RO (if a Medicare contractor BI unit). PSCs and Medicare contractor BI units shall maintain files on the written guidance provided by the OIG/OI.

- Meet (in-person or telephone call) quarterly, or more frequently if necessary, with OIG agents to discuss pending or potential cases.
- Meet (in-person or telephone) regularly with DOJ to enhance coordination with them on current or pending cases.
- Furnish all available information upon request to OIG/OI with respect to excluded providers requesting reinstatement.
- Ensure that all cases that have been identified where a provider consistently fails to comply with the provisions of the assignment agreement are reported by the PSC to the Primary GTL, Associate GTL, and SME; and reported by the Medicare contractor BI unit to the RO.
- Maintain documentation on the number of investigations alleging fraud, the number of cases referred to OIG/OI (and the disposition of those cases), processing time of investigations, and types of violations referred to OIG (e.g., item or service not received, unbundling, waiver of co-payment).
- Conduct investigations (including procedures for reviewing questionable billing codes), make beneficiary contacts (see PIM, chapter 4, §4.7.1 for details concerning investigations), and refer cases to and from the MR unit within your organization.

Ensure that before making an unannounced visit where fraud is suspected, obtain approval from the Primary GTL (if a PSC) or RO (if a Medicare contractor BI unit), and the OI field office, and ensure that any other appropriate investigative agency is consulted with regard to the plan. PSC and Medicare contractor BI unit staff shall never engage in covert operations (e.g., undercover or surveillance activities). If OIG does not give approval, discuss this with the Primary GTL (if a PSC) or RO (if a Medicare contractor) and they will make the final decision.

- Obtain approval by e-mail, letter, or telephone call, and express any concerns (if a telephone call, follow up with a letter or e-mail) to the Primary GTL (if a PSC) or to the RO (if a Medicare contractor BI unit) when the PSC or Medicare contractor BI unit is asked to accompany the OI or any other law enforcement agency when they are going onsite to a provider for the purpose of gathering evidence in a fraud case (e.g., executing a search warrant). However, law enforcement must make clear the role of PSC or Medicare contractor BI unit personnel in the

proposed onsite visit. The potential harm to the case and the safety of PSC or Medicare contractor BI unit personnel shall be thoroughly evaluated. PSC or Medicare contractor BI unit personnel shall properly identify themselves as PSC or Medicare contractor BI unit employees, and under no circumstances shall they represent themselves as law enforcement personnel or special agents. Lastly, under no circumstances shall PSC or Medicare contractor BI unit personnel accompany law enforcement in situations where their personal safety is in question.

The ACs ensure the performance of the functions below and have written procedures for these functions:

- Ensure no payments are made for items or services ordered, referred, or furnished by an individual or entity following the effective date of exclusion (see PIM, chapter 4, §4.19ff for exceptions).
- Ensure all instances where an excluded individual or entity that submits claims for which payment may not be made after the effective date of the exclusion are reported to the OIG (see PIM, chapter 4, §4.19ff).
- Ensure no payments are made for an excluded individual or entity who is employed by a Medicare provider or supplier.

4.2.2.4.1 - Maintain Controlled Filing System and Documentation (Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units shall maintain files on providers who have been the subject of complaints, prepayment flagging, PSC or Medicare contractor BI unit investigations, OIG/OI and/or DOJ investigations, U.S. Attorney prosecution, and any other civil, criminal, or administrative action for violations of the Medicare or Medicaid programs. The files shall contain documented warnings and educational contacts, the results of previous investigations, and copies of complaints resulting in investigations.

The PSCs and Medicare contractors BI units shall set up a system for assigning and controlling numbers at the initiation of investigations, and shall ensure that:

- All incoming correspondence or other documentation associated with an investigation contains the same file number and is placed in a folder containing the original investigation material.
- Investigation files are adequately documented to provide an accurate and complete picture of the investigative effort.
- All contacts are clearly and appropriately documented.

- Each investigation file lists the name, organization, address, and telephone numbers of all persons with whom the PSC or Medicare contractor BI unit can discuss the investigation (including those working within the PSC or Medicare contractor BI unit).

It is important to establish and maintain histories and documentation on all fraud and abuse investigations and cases. PSCs and Medicare contractor BI units shall conduct periodic reviews of the kinds of fraud detected over the past several months to identify any patterns of potential fraud and abuse situations for particular providers. The PSCs and Medicare contractor BI units shall ensure that all evidentiary documents are kept free of annotations, underlining, bracketing, or other emphasizing pencil, pen, or similar marks.

The PSCs and Medicare contractor BI units shall establish an internal monitoring and investigation and case review system to ensure the adequacy and timeliness of fraud and abuse activities.

4.2.2.4.2- File/Document Retention **(Rev. 71, 04-09-04)**

Files/documents shall be retained for 10 years. However, files/documents shall be retained indefinitely and shall not be destroyed if they relate to a current investigation or litigation/negotiation; ongoing Workers' Compensation set aside arrangements, or documents which prompt suspicions of fraud and abuse of overutilization of services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.

4.2.2.5 – Reserved for Future Use **(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)**

4.2.2.5.1 – Reserved for Future Use **(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)**

4.2.2.5.2 – Reserved for Future Use **(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)**

4.2.2.6 – Benefit Integrity Security Requirements **(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)**

The PSCs and Medicare contractors shall ensure a high level of security for this sensitive function. PSCs and Medicare contractor BI unit staff, as well as all other PSC and Medicare contractor employees, shall be adequately informed and trained so that

information obtained by, and stored in, the PSC and Medicare contractor BI unit is kept confidential.

Physical and operational security within the PSC and Medicare contractor BI unit is essential. Operational security weaknesses in the day-to-day activities of PSCs and Medicare contractor BI units may be less obvious and more difficult to identify and correct than physical security. The interaction of PSCs and Medicare contractor BI units with other PSC or Medicare contractor operations, such as the mailroom, could pose potential security problems. Guidelines that shall be followed are discussed below.

Most of the following information can be found in the Business Partners Security Manual, which is located at http://www.cms.hhs.gov/manuals/117_systems_security. It is being reemphasized in this PIM section.

A. Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit Operations

The PSC and Medicare contractor BI unit activities shall be conducted in areas not accessible to the general public and other non-BI Medicare contractor staff. Other requirements shall include:

- Complying with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provisions.
- Limiting access to PSC and Medicare contractor BI unit sites to only those who need to be there on official business. (Tours of the Medicare contractor shall not include the BI unit.)
- Ensuring that discussions of highly privileged and confidential information cannot be overheard by surrounding units. Ideally, the unit does not have an unmonitored entrance or exit to the outside, and has a private office for the manager, for the discussion of sensitive information.
- Ensuring that visitors to the PSC or Medicare contractor BI unit who are there for official purposes unrelated to PSC or Medicare contractor BI unit functions (e.g., cleaning crews, mail delivery personnel, technical equipment repair staff) are not left unobserved.
- Securing the PSC or Medicare contractor BI unit site when it is not occupied by PSC or Medicare contractor BI unit personnel.
- Barring budget constraints and a specific written waiver (exception) from the CMS RO, the Medicare contractor BI unit shall be completely segregated from all other Medicare contractor operations. This segregation shall include closed walls or partitions that prevent unauthorized access or overhearing of sensitive investigative information. Full PSCs are not required to separate their MR and BI

units. However, all BI information shall be kept confidential and secure and shared with MR only on a need-to-know basis.

B. Handling and Physical Security of Sensitive Material

The PSCs and Medicare contractor BI units shall consider all fraud and abuse allegations and associated investigation and case material to be sensitive material. The term “sensitive material” includes, but is not limited to, PSC or Medicare contractor BI unit investigation and case files and related work papers (correspondence, telephone reports, complaints and associated records, personnel files, reports/updates from law enforcement, etc.). Improper disclosure of sensitive material could compromise an investigation or prosecution of a case; it could also cause harm to innocent parties or potentially jeopardize the personal safety of law enforcement (e.g., covert/undercover investigations).

The following guidelines shall be followed:

- Employees shall discuss specific allegations of fraud only within the context of their professional duties and only with those who have a valid need to know. This may include staff from the PSC, AC or Medicare contractor MR or audit units, data analysis, senior management, or corporate counsel.
- Ensure the mailroom, general correspondence, and telephone inquiries procedures maintain confidentiality whenever correspondence, telephone calls, or other communications alleging fraud are received. All internal written operating procedures shall clearly state security procedures.
- Mailroom staff shall be directed not to open BI unit mail in the mailroom, unless the mailroom staff has been directed to do so for safety and health precautions; mail contents shall not be read and shall be held in confidence. Mail being sent to CO, another PSC, or Medicare contractor BI unit shall be marked “personal and confidential,” and shall be addressed to a specific person.
- Where not prohibited by more specialized instructions, sensitive materials may be retained at employees' desks, in office work baskets, and at other points in the office during the course of the normal work day. Access to these sensitive materials is restricted, and such material shall never be left unattended.
- For mail processing sites located in separate PSC or Medicare contractor facilities, the PSC or Medicare contractor shall minimize the handling of BI unit mail by multiple parties before delivery to the PSC or Medicare contractor BI unit.
- When not being used or worked on, such materials shall be retained in locked official repositories such as desk drawers, filing cabinets, or safes. Such

repositories shall be locked at the end of the work day and at other times when immediate access to their contents is not necessary.

- Where such materials are not returned to their official repositories by the end of the normal work day, they shall be placed in some other locked repository (e.g., an employee's desk), locked office, or locked conference room.
- The PSCs and Medicare contractor BI units shall establish procedures for safeguarding keys, combinations, codes and other mechanisms, devices, or methods for achieving access to the work site and to lockable official repositories. The PSCs and Medicare contractor BI units shall limit access to keys, combinations, etc., and maintain a sign-off log to show the date and time when repositories other than personal desk drawers and file cabinets are opened and closed, the documents accessed, and the name of the person accessing the material.
- The PSC and Medicare contractor BI unit shall maintain a controlled filing system (see PIM, chapter 4, §4.2.2.4.1).
- Discarded sensitive information shall be shredded on a daily basis or stored in a locked container for subsequent shredding.

C. Designation of a Security Officer

The PSC or Medicare contractor BI unit manager shall designate an employee to serve as the security officer of the PSC or Medicare contractor BI unit. In addition to their BI duties, the security officer's responsibilities shall include:

- Continuous monitoring of component operations to determine whether the basic security standards noted in B above are being observed.
- Correcting violations of security standards immediately and personally, where practicable and within his/her authority. (This refers to locking doors mistakenly left open; switching off computer equipment left on after the employee using it has departed for the day; locking file cabinets, desk drawers, storage (file) rooms, or safes left unlocked in error; and similar incidents where prompt action is called for.).
- Reporting violations of security standards to the appropriate supervisory authority, so that corrective and/or preventive action can be taken.
- Maintaining a log of all reviews and indicating any violations. The log shall identify the reported issue, the date reported, whom the issue was reported to, and any subsequent resolution. CMS staff may request to review this log periodically.

The PSC or Medicare contractor BI unit manager, compliance manager, or other designated manager shall:

- Review their general office security procedures and performance with the security officer at least once every 6 months.
- Document the results of the review.
- Take such action as is necessary to correct breaches of the security standards and to prevent recurrence. The action taken shall be documented and maintained by the PSC or Medicare contractor BI unit manager.

D. Staffing of the Program Safeguard Contractor or Medicare Contractor Benefit Integrity Unit and Security Training

The PSC or Medicare contractor BI unit manager shall ensure that PSC or Medicare contractor BI unit employees are well-suited to work in this area and that they receive appropriate CMS-required training.

All PSC or Medicare contractor BI unit employees should have easily verifiable character references and a record of stable employment.

The PSC or Medicare contractor BI unit manager shall ensure the following:

- Thorough background and character reference checks, including at a minimum credit checks, shall be performed for potential employees, to verify their suitability for employment with the PSC or Medicare contractor BI unit.
- In addition to a thorough background investigation, potential employees shall be asked whether their employment in the PSC or Medicare contractor BI unit might involve a conflict of interest.
- At the point a hiring decision is made for a PSC or Medicare contractor BI unit position, and prior to the person starting work, the proposed candidate shall be required to fill out a conflict of interest declaration as well as a confidentiality statement.
- Existing employees shall be required annually to fill out a conflict of interest declaration as well as a confidentiality statement.
- Temporary employees, such as those from temporary agencies, and students (non-paid or interns) shall not be employed in the PSC or Medicare contractor BI unit.
- The special security considerations under which the PSC or Medicare contractor BI unit operates shall be thoroughly explained and discussed.

- The hiring of fully competent and competitive staff, and the implementation of measures to foster their retention.

E. Access to Information

The PSC, Medicare contractor, and CMS managers shall have routine access to sensitive information if the PSCs, Medicare contractors, and CMS managers are specifically authorized to work directly on a particular fraud case or are reviewing cases as part of their oversight responsibilities and their performance evaluations. This includes physician consultants who may be assisting the BI unit and whose work may benefit by having specific knowledge of the particular fraud case.

Employees not directly involved with a particular fraud case shall not have routine access to sensitive information. This shall include the following:

- Employees who are not part of the PSC or Medicare contractor BI unit.
- Corporate employees working outside the Medicare division.
- Clerical employees who are not integral parts of the PSC or Medicare contractor BI unit.

Employees should keep in mind that any party that is the subject of a fraud investigation is likely to use any means available to obtain information that could prejudice the investigation or the prosecution of the case. As previously noted and within the above exceptions, PSCs and Medicare contractor BI units shall not release information to any person outside of the PSC or Medicare contractor BI unit and law enforcement staff, including provider representatives and lawyers.

Although these parties may assert that certain information must be provided to them based on their “right to know,” PSCs and Medicare contractor BI units have no legal obligation to comply with such requests. The PSCs and Medicare contractor BI units shall request the caller's name, organization, and telephone number. Indicate that verification of whether or not the requested information is authorized for release must occur before response may be given. Before furnishing any information, however, PSCs and Medicare contractor BI units shall definitely determine that a caller has a “need to know,” and that furnishing the requested information will not prejudice the investigation or case or prove harmful in any other way. Each investigation and case file shall list the name, organization, address and telephone numbers of all persons with whom the PSC or Medicare contractor BI unit can discuss the investigation or case (including those working within the PSC or Medicare contractor BI unit).

While PSC and Medicare contractor BI unit management may have access to general case information, it shall only request on a need-to-know basis specific information about investigations that the PSC or Medicare contractor BI unit is actively working.

The OIG shall be notified if parties without a need to know are asking inappropriate questions. The PSC and Medicare contractor BI unit shall refer all media questions to the CMS press office.

F. Computer Security

Access to BI information in computers shall be granted only to PSC or Medicare contractor BI unit employees. The following guidelines shall be followed:

- Employees shall comply with all parameters/standards in CMS' Information System Security Policy, Standards and Guidelines Handbook and with the System Security Plan (SSP) Methodology.
- Access to computer files containing information on current or past fraud investigations shall be given only to employees who need such access to perform their official duties.
- Passwords permitting access to BI compatible files or databases shall be kept at the level of confidentiality specified by the PSC or Medicare contractor BI unit supervisory staff. Employees entering their passwords shall ensure that it is done at a time and in a manner that prevents unauthorized persons from learning them.
- Computer files with sensitive information shall not be filed or backed up on the hard drive of personal computers, unless one of the two following exceptions are met: 1) the hard drive is a removable one that can be secured at night (the presumption is that a computer with a fixed hard drive is not secure); and 2) the computer can be protected (secured with a "boot" password, a password that is entered after the computer is turned on or powered on). This password prevents unauthorized users from accessing any information stored on the computer's local hard drive(s) (C drive, D drive).
- Another safe and efficient way to preserve data is to back it up. Backing up data is similar to copying it, except that back-up utilities compress the data so that less disk space is needed to store the files.
- Record sensitive information on specially marked floppy disks or CDs and control and file these in a secure container placed in a locked receptacle (desk drawer, file cabinet, etc.). Check computers used for sensitive correspondence to ensure that personnel are not filing or backing up files on the hard drive. The configuration of the software needs to be checked before and after the computer is used to record sensitive information.
- Limit the storage of sensitive information in provider files with open access. Conclusions, summaries, and other data that indicate who will be indicted shall be in note form and not entered into open systems.

- The storage of sensitive information on a Local Area Network (LAN) or Wide Area Network (WAN) is permissible if the two following parameters are satisfied:
 - 1) The LAN/WAN shall be located on a secure Server and the LAN/WAN drive shall be mapped so that only staff from the BI unit have access to the part of the LAN in which the sensitive information is stored.
 - 2) LAN/WAN Administrators have access to all information located on the computer drives they administer, including those designated for the BI unit. As such, LAN/WAN Administrators shall also complete an annual confidentiality statement.

Environmental security measures shall also be taken as follows:

- Electronically recorded information shall be stored in a manner that provides protection from excessive dust and moisture and temperature extremes.
- Computers shall be protected from electrical surges and static electricity by installing power surge protectors.
- Computers shall be turned off if not being used for extended periods of time.
- Computers shall be protected from obvious physical hazards, such as excessive dust, moisture, extremes of temperature, and spillage of liquids and other destructive materials.
- Class C (electrical) fire extinguishers shall be readily available for use in case of computer fire.

G. Telephone Security

The PSC or Medicare contractor BI unit shall implement phone security practices. As stated earlier in this section, the PSC or Medicare contractor BI unit shall discuss investigations and cases only with those individuals that have a **need to know** the information, and shall not divulge information to individuals not personally known to the PSC or Medicare contractor BI unit involved in the investigation of the related issue.

This applies to persons unknown to the PSC or Medicare contractor BI unit who say they are with the FBI, OIG, DOJ, etc. The PSC or Medicare contractor BI unit shall only use CMS, OIG, DOJ, and FBI phone numbers that can be verified. Management shall provide PSC or Medicare contractor BI unit staff with a list of the names and telephone numbers of the individuals of the authorized agencies that the PSC or Medicare contractor BI unit deal with and shall ensure that this list is properly maintained and periodically updated.

Employees shall be polite and brief in responding to phone calls, but shall not volunteer any information or confirm or deny that an investigation is in process. Personnel shall be

cautious of callers who “demand” information and continue to question the PSC or Medicare contractor BI unit after it has stated that it is not at liberty to discuss the matter. Again, it is necessary to be polite, but firmly state that the information cannot be furnished at the present time and that the caller will have to be called back. PSCs and Medicare contractor BI units shall not respond to questions concerning any case being investigated by the OIG, FBI, or any other law enforcement agency. The PSCs and Medicare contractor BI units shall refer them to the OIG, FBI, etc., as appropriate.

The PSCs and Medicare contractor BI units shall transmit sensitive information via facsimile (fax) lines only after it has been verified that the receiving fax machine is secure. Unless the fax machine is secure, PSCs or Medicare contractor BI units shall make arrangements with the addressee to have someone waiting at the receiving machine while the fax is being transmitted. Sensitive information via fax shall not be transmitted when it is necessary to use a delay feature, such as entering the information into the machine's memory.

4.2.3 - Durable Medical Equipment Regional Carrier Fraud Functions (Rev. 71, 04-09-04)

This section applies to both DMERCs and any PSCs performing DMERC BI functions.

On October 1, 1993, separate Medicare carriers were established to pay and review claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). These items are described in further detail at 42 CFR 414.202. As Medicare carriers, DMERCs shall be subject to all BI unit requirements applicable to other carriers.

The fraud investigation and case referral function shall reside in the PSC or DMERC BI unit, which is Medicare-dedicated and physically and organizationally identifiable as a separate unit. The unit shall be led by a full-time BI unit manager. The decisions of the BI unit manager as they pertain to the referral of fraud cases to OIG are not subject to review by DMERC management.

The PSCs and DMERCs shall process all complaints alleging DMEPOS fraud that are filed in their regions in accordance with requirements of PIM Chapter 4, §4.6ff. The BI unit manager has responsibility for all BI unit activity, including the coordination with outside organizations as specified in the PIM Chapter 4, §4.4.2.1.

A. General Requirements

Since the Medicare program has become particularly vulnerable to fraudulent activity in the DMEPOS area, each PSC and DMERC shall:

- Routinely communicate with and exchange information with its PSC, AC or Medicare DMERC MR unit and ensure that referrals for prepayment MR review or other actions are made.

- Consult with DMERC Medical Directors Workgroup in cases involving medical policy or coding issues.
- Fully utilize data available from the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC), to identify items susceptible to fraud.
- Keep other DMERCs, the SADMERC, PSCs, and CMS RO and CO staff informed of its ongoing activities and share information concerning aberrancies identified using data analysis, ongoing and emerging fraud schemes identified, and any other information that may be used to prevent similar activity from spreading to other jurisdictions.

B. Use of National Supplier Clearinghouse Alert Codes

The DMERCs shall initiate appropriate and immediate action in cases where a supplier has had its file appended with a National Supplier Clearinghouse (NSC) alert code that indicates the company may have committed fraud or abuse. The following is a list of general definitions of current NSC alert codes:

A - Possible/suspect fraud and abuse

B - Overpayment - believe uncollectible

C - Violation of supplier standards

D - Violation of disclosure of ownership

E - Violation of participation agreement

F - Sanctioned by the OIG

G - Special review of existing supplier

H - New supplier under review

I - No claims processed by specific DMERC

J - No problem claims

K - Suspended because of fraudulent claims

L - Suspended by DMERC - discovered by DMERC Program Integrity staff investigation

M - Supplier is going through the appeals process

R - Revoked supplier number

4.3 – Medical Review for Benefit Integrity Purposes

(Rev.83 Issued:08-27-04, Effective: September 27, 2004, Implementation: September 27, 2004)

The responsibilities of the PSCs and Medicare contractor BI units include looking for potential fraud. The MR unit's responsibilities include looking for potential errors. PSCs and Medicare contractor BI and MR staff shall work closely together, especially in the areas of:

- Data analysis (PSCs shall follow Chapter 2, §2.3 for sources of data); and
- Identification of potential errors or potential fraud (which shall be referred to the other component).

The PSCs, Medicare contractor BI units, and MR units shall have ongoing discussions and close working relationships regarding situations identified that may be signs of fraud. Intermediaries shall also include the cost report audit unit in the ongoing discussions.

A. Referrals from the Medical Review Unit to the Benefit Integrity Unit

If a provider appears to have knowingly and intentionally furnished services that are not covered, or filed claims for services not furnished as billed, or made any false statement on the claim or supporting documentation to receive payment, the PSC, AC, or Medicare contractor MR unit personnel shall discuss this with the PSC or Medicare contractor BI unit. If the PSC or Medicare contractor BI unit agrees that there is potential fraud, the MR unit shall then make a referral to the PSC or Medicare contractor BI unit for investigation. Provider documentation that shows a pattern of repeated misconduct or conduct that is clearly abusive or potentially fraudulent despite provider education and direct contact with the provider to explain identified errors shall be referred to the PSC or Medicare contractor BI unit.

B. Referrals from the Benefit Integrity Unit to the Medical Review Unit and Other Units

The PSCs and Medicare contractor BI units are also responsible for preventing and minimizing the opportunity for fraud. The PSCs and Medicare contractor BI units shall identify procedures that may make Medicare vulnerable to potential fraud and take appropriate action. For example, PSCs and Medicare contractor BI units may determine that there are problems in the provider enrollment process that make it possible for individuals excluded from the Medicare program to obtain a provider identification number. The PSCs and Medicare contractor BI units shall bring these vulnerabilities to the attention of the AC or Medicare contractor provider enrollment unit.

There may be situations where the PSC and Medicare contractor BI unit initiates the referral of potential fraud to the MR unit for a prepayment or postpayment medical

determination. For example, the Medicare contractor BI unit may request the MR unit review claims and corresponding records associated with an investigation to determine if the services were performed at the level billed. The MR unit shall then return the investigation with their determination to the Medicare contractor BI unit.

Therefore, when the MR unit is requested by the Medicare contractor BI unit to perform medical review as part of an investigation, the MR costs shall be charged to the BI line (Activity Code 23007 in the BPR).

The PSC shall work with its own nurses to perform these types of reviews.

4.4 - Other Program Integrity Requirements (Rev. 71, 04-09-04)

4.4.1 - Requests for Information From Outside Organizations *(Rev. 144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)*

Federal and state and local law enforcement agencies may seek beneficiary and provider information to further their investigations or prosecutions of individuals or businesses alleged to have committed health care fraud and other crimes for which medical records may be sought as evidence. When these agencies request that a PSC or Medicare contractor BI unit disclose beneficiary records or provider information, the responsive disclosure shall comply with applicable federal law as required by the HIPAA Business Associate provision of the PSC or Medicare contractor BI unit's contract. Federal law will dictate whether, and how much, requested information can be disclosed and disclosure will be contingent on the purpose for which it is sought, and whether information is sought about beneficiaries or providers. Certain general information, for example, which does not include specific beneficiary identifiers may be shared with a broader community (including private insurers), such as the general nature of how fraudulent practices were detected, the actions being taken, and aggregated data showing trends and/or patterns.

In deciding to share information voluntarily or in response to outside requests, the PSC or Medicare contractor BI unit shall carefully review each request to ensure that disclosure would not violate the requirements of the Privacy Act of 1974 (5 U.S.C. 552a) and/or the Privacy Rule (45 CFR, Parts 160 and 164) implemented under the HIPAA. Both the Privacy Act and the Rule seek to strike a balance that allows the flow of health information needed to provide and promote high quality health care while protecting the privacy of people who seek this care. In addition, they provide individuals with the right to know with whom their personal information has been shared and this, therefore, necessitates the tracking of any disclosures of information by the PSC or Medicare contractor BI unit. PSC and Medicare contractor BI unit questions concerning what information may be disclosed under the Privacy Act or Privacy Rule shall be directed to regional office Freedom of Information Act (FOIA)/privacy coordinator. Ultimately, the

authority to release information from a Privacy Act System of Records to a third party rests with the system manager/business owner of the system of records.

The HIPAA Privacy Rule establishes national standards for the use and disclosure of individuals' health information (also called protected health information) by organizations subject to the Privacy Rule (which are called "covered entities"). As a "business associate" of CMS, PSCs and Medicare contractor BI units are contractually required to comply with the HIPAA Privacy Rule. The Privacy Rule restricts the disclosure of any information, in any form, that can identify the recipient of medical services unless that disclosure is expressly permitted under the Privacy Rule. Two of the circumstances in which the Privacy Rule allows disclosure are for "health oversight activities" (45 CFR 164.512(d)) and "law enforcement purposes" (45 CFR 164.512 (f)), provided the disclosure meets all the relevant prerequisite procedural requirements in those subsections. Generally, protected health information may be disclosed to a health oversight agency (as defined in 45 CFR 164.501) for purposes of health oversight activities authorized by law, including administrative, civil, and criminal investigations necessary for appropriate oversight of the health care system (45 CFR 164.512(d)). The Department of Justice (DOJ), through its United States Attorneys' Offices and its headquarters-level litigating divisions, the FBI, the Department of Health and Human Services Office of Inspector General (DHHS -OIG), and other federal, state, or local enforcement agencies, are acting in the capacity of health oversight agencies when they are investigating fraud against Medicare, Medicaid, or other health care insurers or programs.

The Rule also permits disclosures for other law enforcement purposes that are not health oversight activities but involve other specified law enforcement activities for which disclosures are permitted under HIPAA, which include a response to grand jury or administrative subpoenas and court orders, and for assistance in locating and identifying material witnesses, suspects, or fugitives. The complete list of circumstances that permit disclosures to a law enforcement agency is detailed in 45 CFR 164.512(f). Furthermore, the Rule permits covered entities, and business associates acting on their behalf, to rely on the representation of public officials seeking disclosures of protected health information for health oversight or law enforcement purposes provided that the identities of the public officials requesting the disclosure have been verified by the methods specified in the Rule (45 CFR 164.514(h)).

The Privacy Act of 1974 protects information about an individual that is collected and maintained by a federal agency in a system of records. A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency. This includes, but is not limited to, information about educational background, financial transactions, medical history, criminal history, or employment history that contains a name or an identifying number, symbol, or other identifying particulars assigned to the individual. The identifying particulars can be a finger or voiceprint or a photograph. A "system of records" is any group of records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

For example, Medicare beneficiary data used by the PSC or Medicare contractor BI unit are maintained in a CMS “system of records” covered by the Privacy Act.

Information from some systems of records may be released only if the disclosure would be consistent with “routine uses” that CMS has issued and published. Routine uses specify who may be given the information and the basis or reason for access that must exist. Routine uses vary by the specified system of records, and a decision concerning the applicability of a routine use lies solely in the purview of the system’s manager for each system of records. In instances where information is released as a routine use, the Privacy Act and Privacy Rule remain applicable. The Federal Register system of records notices maintained by CMS may be found on the Web site at

<http://www.cms.hhs.gov/privacyact/tblsors.asp>. For example, the Department of Health and Human Services has published a routine use which permits the disclosure of personal information concerning individuals to the Department of Justice, as needed for the evaluation of potential violations of civil or criminal law and for detecting, discovering, investigating, litigating, addressing, or prosecuting a violation or potential violation of law, in health benefits programs administered by CMS. See 63, Fed. Reg. 38414, (July 16, 1998).

A. Requests from Private, Non-Law Enforcement Agencies

Generally, PSCs and Medicare contractor BI units may furnish information on a scheme (e.g., where it is operating, specialties involved). Neither the name of a beneficiary or suspect can be disclosed. If it is not possible to determine whether or not information is releasable to an outside entity, Medicare contractors shall contact the CMS RO for further direction. Similarly, PSCs shall contact their Primary Government Task Leader (GTL), Associate GTL, and SME for any further guidance.

B. Requests from Medicare Contractors and Program Safeguard Contractors

The PSCs and Medicare contractor BI units may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to any PSC, AC, or Medicare contractor BI unit. PSCs, ACs, and Medicare contractor BI units are “business associates” of CMS under the Privacy Rule and thus are permitted to exchange information necessary to conduct health care operations. If the request concerns cases already referred to the OIG/OI, PSCs or Medicare contractor BI units shall refer the requesting PSC or Medicare contractor BI unit to the OIG/OI.

C. Requests for Information from Qualified Independent Contractors

When a Qualified Independent Contractor (QIC) receives a request for reconsideration on a claim arising from a PSC review determination, it shall first coordinate with the AC to obtain any and all records and supporting documentation that the PSC provided to the AC in support of the AC’s first level appeals activities (redeterminations). As necessary, the QIC may also contact the PSC to discuss materials obtained from the AC and/or obtain additional information to support the QIC’s reconsideration activities. The QIC shall

send any requests to the PSC for additional information via electronic mail, facsimile, and/or telephone.

NOTE: Individually identifiable beneficiary information should not be given in an e-mail.

These requests should be minimal. The QIC shall include in its request a name, phone number, and address to which the requested information shall be sent and/or follow-up questions shall be directed. The PSC shall document the date of the QIC's request and send/transmit the requested information within 7 calendar days of the date of the QIC's request. The date of the QIC's request is defined as the date the phone call is made (if a message is left, it is defined as the date the message was left) or the date of the e-mail request.

If a QIC identifies a situation of potential fraud and abuse, they shall immediately refer any all related information to the appropriate PSC for further investigation. Refer to PIM, Exhibit 38, for QIC task orders and jurisdictions.

D. Quality Improvement Organizations and State Survey and Certification Agencies

The PSCs and Medicare contractor BI units may furnish requested specific information on ongoing fraud investigations and on individually identifiable protected health information to the QIOs and State Survey and Certification Agencies. The functions QIOs perform for CMS are required by law, thus the Privacy Rule permits disclosures to them. State Survey and Certification Agencies are required by law to perform inspections, licensures, and other activities necessary for appropriate oversight of entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards, thus the Privacy Rule permits disclosures to them. If the request concerns cases already referred to the OIG/OI, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

E. State Attorneys General and State Agencies

The PSCs and Medicare contractor BI units may furnish requested specific information on ongoing fraud investigations to state Attorneys General and to state agencies. Releases of information to these entities in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. See subsection H below and PIM Exhibit 25, for guidance on how requests should be structured to comply with the Privacy Rule. PSCs and Medicare contractor BI units may, at their discretion, share Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

F. Request from Medicaid Fraud Control Units

Under current Privacy Act requirements applicable to program integrity investigations, PSCs and Medicare contractor BI units may respond to requests from Medicaid Fraud Control Units (MFCUs) for information on current investigations. Releases of information to MFCUs in connection with their responsibility to investigate, prosecute, enforce, or implement a state statute, rule or regulation may be made as a routine use under the Privacy Act of 1974, as amended; 5 USC §552a(b)(3) and 45 CFR Part 5b Appendix B (5). See subsection H below for further information regarding the Privacy Act requirements. If individually identifiable protected health information is requested, the disclosure shall comply with the Privacy Rule. See subsection H below and PIM Exhibit 25, for guidance on how requests should be structured to comply with the Privacy Rule. PSCs and Medicare contractor BI units may, at their discretion, share Exhibit 25 with the requestor as a template to assist them in preparing their request. If the request concerns cases already referred to the OIG/OI, PSCs and Medicare contractor BI units shall refer the requestor to the OIG/OI.

G. Requests from OIG/OI for Data and Other Records

The PSCs and Medicare contractor BI units shall provide the OIG/OI with requested information, and shall maintain cost information related to fulfilling these requests. *Such requested information may include law enforcement requests for voluntary refund data (refer to Chapter 4, §4.16 for information on voluntary refunds).* If major/costly systems enhancements are required to fulfill a request, the PSCs shall discuss the request with the Primary GTL, Associate GTL, and SME before fulfilling the request, and the Medicare contractor BI units shall discuss the request and the cost with the RO before fulfilling the request. These requests generally fall into one of the following categories:

Priority I – This type of request is a top priority request requiring a quick turnaround. The information is essential to the prosecution of a provider. Information or material is obtained from the PSC's or Medicare contractor BI unit's files. Based on review of its available resources, the PSC or Medicare contractor BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The PSCs and Medicare contractors BI units shall respond to such requests within 30 days whenever possible. If that timeframe cannot be met, the PSC or Medicare contractor BI unit shall notify the requesting office as soon as possible (but not later than 30 days) after receiving the request. PSCs and Medicare contractor BI units shall include an estimate of when all requested information will be supplied. This timeframe applies to all requests with the exception of those that require Data Extract Software System (DESY) access to NCH.

Priority II – This type of request is less critical than a Priority I request. Development requests may require review or interpretation of numerous records, extract of records from retired files in a warehouse or other archives, or soliciting information from other sources. Based on the review of its available resources, the PSC or Medicare contractor BI unit shall inform the requestor what, if any, portion of the request can be provided. The PSC or Medicare contractor BI unit shall provide the relevant data, reports, and findings to the requesting agency in the format(s) requested.

The PSCs and Medicare contractor BI units shall respond to such requests within 45 calendar days, when possible. If that timeframe cannot be met, the PSC or Medicare contractor BI unit shall notify the requesting office within the 45-day timeframe, and include an estimate of when all requested information will be supplied. This timeframe applies to all requests with the exception of those that require DESY access to national claims history (NCH).

Disclosures of information to the OIG/OI shall comply with the Privacy Rule and Privacy Act. To comply with the Privacy Act, the OIG/OI must make all data requests using the form entitled, *Office of Inspector General, Office of Investigations Data Use Agreement* (see Exhibit 37). *In order for CMS to track disclosures that are made to law enforcement and health oversight agencies, PSCs and Medicare contractor BI units shall send a copy of all requests for data to the CMS Privacy Officer at the following address:*

*Centers for Medicare & Medicaid Services
Director of Division of Privacy Compliance Data Development
and CMS Privacy Officer
Mail Stop N2-04-27
7500 Security Boulevard
Baltimore, Maryland 21244*

H. Procedures for Sharing CMS Data With the Department of Justice

In April 1994, CMS entered into an interagency agreement with the DHHS Office of the Inspector General and the DOJ that permitted CMS contractors (PSCs and Medicare contractor BI units) to furnish information, including data, related to the investigation of health care fraud matters directly to DOJ that previously had to be routed through OIG (see PIM Exhibit 35). This agreement was supplemented on April 11, 2003, when in order to comply with the HIPAA Privacy Rule, DOJ issued procedures, guidance, and a form letter for obtaining information (see PIM Exhibit 25). CMS and DOJ have agreed that DOJ requests for individually identifiable health information will follow the procedures that appear on the form letter (see PIM Exhibit 25). The 2003 form letter must be customized to each request. The form letter mechanism is not applicable to requests regarding Medicare Secondary Payer (MSP) information, unless the DOJ requester indicates he or she is pursuing an MSP fraud matter.

The PIM, Exhibit 25, contains the entire document issued by the DOJ on April 11, 2003. PSCs and Medicare contractor BI units shall familiarize themselves with the instructions

contained in this document. Data requests for individually identifiable protected health information related to the investigation of health care fraud matters will come directly from those individuals at FBI or DOJ who are involved in the work of the health care oversight agency (including, for example, from an FBI agent, AUSAs, or designee such as an analyst, auditor, investigator, or paralegal). For example, data may be sought to assess allegations of fraud; examine billing patterns; ascertain dollar losses to the Medicare program for a procedure, service, or time period; *determine the nature and extent of a provider's voluntary refund(s)*; or conduct a random sample of claims for medical review. The law enforcement agency should begin by consulting with the appropriate Medicare contractor (usually the PSC, but possibly also the carrier, fiscal intermediary, or CMS) to discuss the purpose or goal of the data request. Requests for cost report audits and/or associated documents shall be referred directly to the appropriate FI.

The PSCs and Medicare contractor BI units shall discuss the information needed by DOJ and determine the most efficient and timely way to provide the information. When feasible, the PSC and Medicare contractor BI unit will use statistical systems to inform DOJ of the amount of dollars associated with their investigation, and the probable number of claims to expect from a claims level data run. PSCs and Medicare BI units shall obtain and transmit relevant statistical information to DOJ (as soon as possible but no later than five (5) working days) and advise DOJ of the anticipated volume, format, and media to be used (or alternative options, if any) for fulfilling a request for claims data.

The DOJ will confirm whether a request for claims data remains necessary based on the results of statistical analysis. If so, DOJ will discuss with CMS issues involving the infrastructure and data expertise necessary to analyze and further process the data that CMS will provide to DOJ.

If DOJ confirms that claims data are necessary, DOJ will prepare a formal request letter to the PSC or Medicare contractor BI unit with existing DOJ guidance (Exhibit 25).

The PSCs and Medicare contractor BI units will provide data to DOJ, when feasible in a format to be agreed upon by the PSCs or Medicare contractor BI units and DOJ. Expected time frames for fulfilling DOJ claims level data requests will depend on the respective source(s) and duration of time for which data are sought, as follows:

PSC or Medicare contractor BI unit data requests that do not require coordination with other Medicare contractors and/or CMS shall be provided within 30 days of the request. (Changes to Exhibit 25 will be forthcoming by DOJ, but this timeframe and the timeframe below shall be followed and not the timeframe specified in the current Exhibit 25.)

PSC or Medicare contractor BI unit data requests that require coordination with other Medicare contractors and/or CMS (except for the bullet directly below) shall be provided within 45 days of the request.

PSCs or Medicare contractor BI units data requests that require Data Extract Software System (DESY) access to the National Claims History (NCH) files will have an undetermined response time.

Emergency requests require coordination with Headquarters DOJ and CMS staff.

Once the format is agreed upon, the law enforcement agency will send the signed 2003 form letter, identifying the appropriate authority under which the information is being sought and specifying the details of the request to the PSC or Medicare contractor BI unit. A request for data that is submitted on the 2003 form letter is considered to be a Data Use Agreement (DUA) with CMS. In order for CMS to track disclosures that are made to law enforcement and health oversight agencies, PSCs and Medicare contractor BI units shall send a copy of all requests for data to the CMS Privacy Officer at the following address:

Centers for Medicare & Medicaid Services
Director of Division of Privacy Compliance Data Development
and CMS Privacy Officer
Mail Stop N2-04-27
7500 Security Blvd.
Baltimore, MD. 21244

The CMS has established a cost limit of \$200,000 for any individual data request. If the estimated cost to fulfill any one request is likely to meet or exceed this figure, a CMS representative will contact the requestor to explore the feasibility of other data search and/or production options. Few, if any, individual DOJ requests will ever reach this threshold. In fact, an analysis of DOJ requests fulfilled by CMS' central office over the course of 1 year indicates that the vast majority of requests were satisfied with a minimum of expense. Nevertheless, CMS recognizes that PSCs and Medicare contractor BI units may not have sufficient money in their budgets to respond to DOJ requests. In such cases, Medicare contractor BI units are advised to submit to CMS a Supplementary Budget Request (SBR). PSCs shall contact their Primary GTLs, Associate GTLs, and SMEs. To facilitate CMS' ability to track the frequency and burden of DOJ requests, the Medicare contractor BI unit shall maintain and submit to CMS, on a quarterly basis, a log of DOJ data requests that has been itemized to show costs for filling each request. This report should be in the form of an Excel spreadsheet (see PIM Exhibit 26) and shall include, at a minimum, the following fields:

1. Medicare contractor name and identification number
2. Date of DOJ request
3. Nature of DOJ request and DOJ tracking number, if provided
4. Cost to fulfill request

5. Medicare contractor's capacity to fill request, including date of SBR submission, if necessary

The report shall be sent to the following address:

Director, Division of Benefit Integrity Management Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C3-02-16
Baltimore, Maryland 21244

I. Law Enforcement Requests for Medical Review

The PSCs and Medicare contractor BI units shall not send document request letters or go on site to providers to obtain medical records solely at the direction of law enforcement. However, if law enforcement furnishes the medical records and requests the PSC or Medicare contractor BI unit to review and interpret medical records for them, the PSC and Medicare contractor BI unit shall require law enforcement to put this request in writing. At a minimum, this request shall include the following information:

The nature of the request (e.g., what type of service is in question and what should the reviewer be looking for in the medical record)

The volume of records furnished

Due dates

Format required for response

The PSC shall present the written request to the Primary GTL, Associate GTL, and SME and the Medicare contractor BI unit shall present the written request to their RO prior to fulfilling the request. Each written request will be considered on a case-by-case basis to determine whether the request will be approved.

J. Law Enforcement Requests for PSC Audits of Medicare Provider Cost Reports Relating to Fraud

If law enforcement requests the PSC to perform an audit of a Medicare provider's cost report for fraud, the PSC shall consult with the AC to inquire if an audit of the cost report has already been performed. The PSC shall also consult with the Primary GTL, Associate GTL, and SME. The PSC shall provide the Primary GTL, Associate GTL, and SME with the basis for the law enforcement request and a detailed cost estimate to complete the audit. If the Primary GTL, Associate GTL, and SME approve the audit, the PSC shall perform the audit within the timeframe and cost agreed upon with law enforcement.

K. Requests from Law Enforcement for Information Crossing Several PSC Jurisdictions

If a PSC receives a request from law enforcement for information that crosses several PSC jurisdictions, the PSC shall respond back to the requestor specifying that they will be able to assist them with the request that covers their jurisdiction. However, for the information requested that is covered by another PSC jurisdiction, the PSC shall provide the requestor with the correct contact person for the inquiry, including the person's name and telephone number. Furthermore, the PSC shall inform the requestor that the Director of the Division of Benefit Integrity Management Operations at CMS CO is the contact person in case any additional assistance is needed. The PSC shall also copy their GTLs and SMEs on their response back to law enforcement for these types of cross jurisdictional requests.

L. Privacy Act Responsibilities

The 1994 Agreement and the 2003 form letter (see PIM Exhibits 35 and 25 respectively) are consistent with the Privacy Act. Therefore, requests that appear on the 2003 form letter do not violate the Privacy Act. The Privacy Act of 1974 requires federal agencies that collect information on individuals that will be retrieved by the name or another unique characteristic of the individual to maintain this information in a system of records.

The Privacy Act permits disclosure of a record, without the prior written consent of an individual, if at least one of twelve disclosure provisions apply. Two of these provisions, the "routine use" provision and/or another "law enforcement" provision, may apply to requests from DOJ and/or FBI.

Disclosure is permitted under the Privacy Act if a routine use exists in a system of records.

Both the Intermediary Medicare Claims Records, System No., 09-70-0503, and the Carrier Medicare Claims Records, System No. 09-70-0501, contain a routine use that permits disclosure to:

"The Department of Justice for investigating and prosecuting violations of the Social Security Act to which criminal penalties attach, or other criminal statutes as they pertain to Social Security Act programs, for representing the Secretary, and for investigating issues of fraud by agency officers or employees, or violation of civil rights."

The CMS Utilization Review Investigatory File, System No. 09-70-0527, contains a routine use that permits disclosure to "The Department of Justice for consideration of criminal prosecution or civil action."

The latter routine use is more limited than the former, in that it is only for "consideration of criminal or civil action." It is important to evaluate each request based on its applicability to the specifications of the routine use.

In most cases, these routine uses will permit disclosure from these systems of records; however, each request should be evaluated on an individual basis.

Disclosure from other CMS systems of records is not permitted (i.e., use of such records compatible with the purpose for which the record was collected) unless a routine use exists or one of the 11 other exceptions to the Privacy Act applies.

The law enforcement provision may apply to requests from the DOJ and/or FBI. This provision permits disclosures “to another agency or to an instrumentality of any jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought.”

The law enforcement provision may permit disclosure from any system of records if all of the criteria established in the provision are satisfied. Again, requests should be evaluated on an individual basis.

To be in full compliance with the Privacy Act, all requests must be in writing and must satisfy the requirements of the disclosure provision. However, subsequent requests for the same provider that are within the scope of the initial request do not have to be in writing. PSCs shall refer requests that raise Privacy Act concerns and/or issues to the Primary GTL, Associate GTL, and SME for further consideration, and Medicare contractor BI units shall refer requests to their CMS RO.

M. Duplicate Requests for Information

The DOJ and the OIG will exchange information on cases they are working on to prevent duplicate investigations. If the PSC or Medicare contractor BI unit receives duplicate requests for information, the PSC or Medicare contractor BI unit shall notify the requestors. If the requestors are not willing to change their requests, the PSC or Medicare contractor BI unit shall ask the Primary GTL, Associate GTL, and SME (if a PSC) or CMS RO employee (if a Medicare contractor BI unit) for assistance.

N. Reporting Requirements

For each data request received from DOJ, PSCs and Medicare contractor BI units shall maintain a record that includes:

- The name and organization of the requestor

- The date of the written request (all requests must be in writing)

- The nature of the request

Any subsequent modifications to the request

Whether the RO, Primary GTL, Associate GTL, and SME had to intervene on the outcome (request fulfilled or not fulfilled)

The cost of furnishing a response to each request

The Medicare contractor shall report the data to the RO when requested by the RO. This data will be used to assess budget requirements.

4.4.1.1 - Sharing Fraud Referrals Between the Office of the Inspector General and the Department of Justice
(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The PSCs and Medicare contractor BI units shall include two copies of the summary report of investigation with each fraud referral made to the OIG. As of October 18, 1999, the OI will provide one copy of the summary report of investigation along with all related information within 5 working days to the FBI Headquarters. The referral information received from the PSC or Medicare contractor BI unit includes all the information relevant to the potential fraud case. The OI will copy the PSC or Medicare contractor BI unit fraud referral to the FBI and will notify the FBI of any action they will take on the referral. The OI field offices will no longer forward health care fraud referrals directly to the local FBI field office. The OI will notify PSCs and Medicare contractor BI units of its decision on the fraud referral, with specific instructions on all matters related to the referral, within 90 calendar days.

Upon receipt of fraud referrals, the OI regional field offices are required to perform one or more of the following:

- Open an investigation
- Return the matter to the PSC or Medicare contractor BI unit for further development
- Forward the referral to the local FBI office or other law enforcement agency for investigation
- Close the case with no action necessary and refer the case back to the PSC or Medicare contractor BI unit for administrative action

The PSC or Medicare contractor BI unit shall follow the instructions in PIM, Chapter 4, §4.18.1, to follow up with the OI to determine their decision after the 90-calendar-day period. The PSC or Medicare contractor BI unit is encouraged to have dialogue with law enforcement during investigations, and to discuss fraud referrals at periodic meetings. If the OI does not give the PSC or Medicare contractor BI unit a definite answer after the

90-day period, the PSC or Medicare contractor BI unit shall contact the RO to help obtain the needed information, and the PSC shall contact the Primary GTL, Associate GTL, and SME. The FBI will notify the PSC or Medicare contractor BI unit of their action on the PSC or Medicare contractor BI unit fraud referral within 45 calendar days from the day the FBI receives referral from the OI. However, if the PSC or Medicare contractor BI unit has not received feedback at the end of the 45-calendar-day period, the PSC or Medicare contractor BI unit may contact the applicable local FBI field office for a status. The PSC or Medicare contractor BI unit shall not contact the FBI Headquarters for a status of the fraud referral. In the case of multiple providers or servicing PSCs or Medicare contractor BI units, the FBI will notify the PSC or Medicare contractor BI unit that initiated the referral as to the decision.

4.4.2 - Program Safeguard Contractor and Medicare Contractor Coordination with Other Program Safeguard Contractors and Medicare Contractors

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

The PSCs and Medicare contractor BI units shall coordinate with other PSCs and Medicare contractor BI units within their service area. This includes sharing local coverage determinations (LCDs), and collaborating on abusive billing situations that may be occurring in multi-state PSCs or Medicare contractor BI units. Coordination is also necessary because certain findings of fraud involving a provider could have a direct effect on payments made by ACs or Medicare contractors. PSCs and Medicare contractors use the appropriate staff member(s) to share information with Medicare contractors not in contiguous states.

4.4.2.1 - Program Safeguard Contractor and Medicare Contractor Coordination with Other Entities

(Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units shall establish and should maintain formal and informal communication with state survey agencies, OIG, DOJ, General Accounting Office (GAO), Medicaid, other Medicare contractors (intermediaries with carriers and vice versa), other PSCs, and other organizations as applicable to determine information that is available and that should be exchanged to enhance PI activities.

If a PSC or Medicare contractor BI unit identifies a potential quality problem with a provider or practitioner in its area, it shall refer such cases to the appropriate entity, be it the QIO, state medical board, state licensing agency, etc. Any provider-specific information shall be handled as confidential information.

4.4.3 - Beneficiary, Provider, Outreach Activities

(Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units should produce a wide variety of outreach items and materials for beneficiary and provider education and awareness. These items should include: brochures, flyers, stuffers, pens, pencils, newspaper advertisements, public service announcements, pamphlets, and videos, to list a few.

4.5 - The ARGUS System **(Rev. 71, 04-09-04)**

ARGUS is a user-friendly personal computer software package developed by the OIG both to access provider claims data and to limit the need for the OIG to submit multiple requests to carriers for claims data. ARGUS is a useful tool for reviewing relationships of data that carriers have available. The billing practices of physicians, for example, can be compared to that of their peers as a means of detecting aberrant behavior. The OIG has trained a representative from each Medicare contractor BI unit to use ARGUS.

The OIG and other authorized federal law enforcement agencies request claims data as they have in the past, but do not specify how the data is to be sorted. They specify the providers and the dates of service. ARGUS, which is written in DBASE, utilizes line item claims data provided by Medicare carriers in a simple ASCII format and separates the incoming data into database fields.

An investigative file in ARGUS is a database file consisting of individual line items of service taken from health insurance claims forms. Each line item consists of 29 fields and 160 bytes of information. Line items from a single provider or from multiple providers involved in a specific investigation may be combined into one ARGUS file.

The PSCs are not required to have ARGUS, but they may obtain it if they wish.

When PSCs and Medicare contractor BI units receive a request for data utilizing ARGUS, they complete the data elements contained in PIM Exhibit 34 (ARGUS Field Descriptions and Codes), in the order shown, and consistent with the following data conventions:

- All character fields are left-justified
- Leading zeros and blanks are omitted
- All numeric fields are right-justified
- Money fields are shown as \$\$\$cc (no decimal point)
- All dates are shown as YYMMDD

Data are to be furnished in the above format on 3½-inch, high-density floppy disks or a compact disk. If the data does not fit on the 3½-inch disk without data compression,

carriers compress the data using the PKZIP compression utility. Data will be transmitted to OIG in a format consistent with CMS's security requirements.

4.6 - Complaints

(Rev. 71, 04-09-04)

4.6.1 - Definition of a Complaint

(Rev. 71, 04-09-04)

A complaint is a statement, oral or written, alleging that a provider, supplier, or beneficiary received a Medicare benefit of monetary value, directly or indirectly, overtly or covertly, in cash or in kind, to which he or she is not entitled under current Medicare law, regulations, or policy. Included are allegations of misrepresentation and violations of Medicare requirements applicable to persons or entities that bill for covered items and services. Examples of complaints include:

- Allegations that items or services were not received.
- Allegations that items or services were not furnished as shown on the Explanation of Medicare Benefits (EOMB), Notice of Utilization (NOU), or Medicare Summary Notice (MSN), or that the services were not performed by the provider shown.
- Allegations that a provider is billing Medicare for a different item or service than that furnished.
- Allegations that a provider or supplier has billed both the beneficiary and Medicare for the same item or service.
- Allegations regarding waiver of co-payments or deductibles.
- Allegations that a supplier or provider has misrepresented itself as having an affiliation with an agency or department of the state, local, or federal government, whether expressed or implied.
- Beneficiary inquiries concerning payment for an item or service, that in his/her opinion, far exceeds reasonable payment for the item or service that the beneficiary received (e.g., the supplier or physician has "up-coded" to receive higher payment).

The following are not examples of a fraud complaint:

- Complaints or inquiries regarding Medicare coverage policy;

- Excessive charges;
- Complaints regarding the appeals process;
- Complaints over the status of a claim;
- Requests for an appeal or reconsideration; or
- Complaints concerning providers or suppliers (other than those complaints meeting the criteria established above) that are general in nature and are policy- or program-oriented.

Complaints alleging malpractice or poor quality of care may or may not involve a fraudulent situation. These shall be reviewed and determined on a case-by-case basis. Refer complaints alleging poor quality of care to the Medicare/Medicaid survey and certification agencies and the QIO.

4.6.2 - Complaint Screening

(Rev. 127, Issued: 10-28-05; Effective/Implementation Dates: 11-28-05)

This section delineates the responsibility for PSCs, ACs, and Medicare contractors with regard to screening complaints alleging fraud and abuse. This supersedes any language within the Joint Operating Agreements (JOAs).

A. Medicare Contractor and Affiliated Contractor Responsibilities

The AC and the Medicare contractor shall be responsible for screening all complaints of potential fraud and abuse. This screening shall occur in the two phases described below.

Initial Screening

Customer service representatives (CSRs) shall try to resolve as many inquiries as possible in the Initial Screening with data available in their desktop system. The CSRs shall send an acknowledgement or resolution letter for written requests within 45 business days of the receipt date stamped in the mailroom, unless the written request can be acknowledged or resolved over the telephone. The following are some scenarios that a CSR may receive and resolve in the initial phone call rather than refer to second-level screening (this is not an all-inclusive list):

Lab Tests – CSRs shall ask the caller if they recognize the referring physician. If they do, remind the caller that the referring physician may have ordered some lab work for them. The beneficiary usually does not have contact with the lab because specimens are sent to the lab by the referring physician office. (Tip: ask if they remember the doctor withdrawing blood or obtaining a tissue sample on their last visit.)

Anesthesia Services - CSRs shall check the beneficiary claims history for existing surgery or assistant surgeon services on the same date. If a surgery charge is on file, explain to the caller that anesthesia service is part of the surgery rendered on that day.

Injections - CSRs shall check the beneficiary claim history for the injectable (name of medication) and the administration. Most of the time, administration is not payable (bundled service) (Part B only). There are very few exceptions to pay for the administration.

Services for Spouse - If the beneficiary states that services were rendered to his/her spouse and the Health Insurance Claim Numbers (HICNs) are the same, with a different suffix, the CSR shall initiate the adjustment and the overpayment process.

Billing Errors - If the beneficiary states that he/she already contacted his/her provider and the provider admitted there was a billing error, and the check is still outstanding, the CSR shall follow the normal procedures for resolving this type of billing error.

Services Performed on a Different Date - The beneficiary states that service was rendered, but on a different date. This is not a fraud issue. An adjustment to the claim may be required to record the proper date on the beneficiary's file.

Incident to Services - Services may be performed by a nurse in a doctor's office as "incident to." These services are usually billed under the physician's provider identification number (PIN) (e.g., blood pressure check, injections, etc.). These services may be billed under the minimal Evaluation and Management codes.

Billing Address vs. Practice Location Address - The CSR shall check the practice location address, which is where services were rendered. Many times the Medicare Summary Notice will show the billing address and this causes the beneficiary to think it is fraud.

X-rays with Modifier 26 - The CSRs shall ask the caller if he/she recognizes the referring physician. If so, the CSR shall explain to the caller that whenever modifier 26 is used, the patient has no contact with the doctor. The CSR shall further explain that the provider billing with modifier 26 is the one interpreting the test for the referring physician.

Initial Screening activities shall be charged to Activity Code 13002 (Beneficiary Written Inquiries), Activity Code 13005 (Beneficiary Telephone Inquiries), Activity Code 33001 (Provider Telephone Inquiries), or Activity Code 33002 (Provider Written Inquiries) (whichever is the most applicable).

The CSRs shall use proper probing questions and shall utilize claim history files to determine if the case needs to be referred for second-level screening.

Any provider inquiries regarding potential fraud and abuse shall be forwarded immediately to the second-level screening staff for handling.

Any immediate advisements (e.g., inquiries or allegations by beneficiaries or providers concerning kickbacks, bribes, a crime by a Federal employee, indications of contractor employee fraud (e.g., altering claims data or manipulating it to create preferential treatment to certain providers; improper preferential treatment in collection of overpayments; embezzlement)) shall be forwarded immediately to the second-level screening staff for handling.

The initial screening staff shall maintain a log of all potential fraud and abuse inquiries. At a minimum, the log shall contain the following information:

Beneficiary name

Provider Name

Beneficiary HIC#
Nature of the Inquiry

Date of the Inquiry

Internal Tracking Number

Date Referred to the Second Level Screening Staff

Date Closed

Second-Level Screening

When the complaint/inquiry cannot be resolved by the CSR, the issue shall be referred for more detailed screening, resolution, or referral, as appropriate, within the AC or Medicare contractor. If the second level screening staff is able to resolve the inquiry without referral, they shall send a resolution letter, unless it can be resolved by telephone, within 45 business days of receipt from the initial screening staff, or within 30 business days of receiving medical records and/or other documentation, whichever is later. The second-level screening staff shall maintain a log of all potential fraud and abuse inquiries received from the initial screening staff. At a minimum, the log shall include the following information:

Beneficiary name

Provider name

Beneficiary HIC#

Nature of the Inquiry

Date received from the initial screening staff

Date referral is forwarded to the Medicare contractor BI unit or the date it is sent to the PSC

Destination of the referral (i.e., name of PSC or Medicare contractor BI unit)

Documentation that an inquiry received from the initial screening staff was not forwarded to the PSC or Medicare Contractor BI Unit and an explanation why (e.g., inquiry was misrouted or inquiry was a billing error that should not have been referred to the second-level screening staff)

Date inquiry is closed

The AC or Medicare contractor staff shall call the beneficiary or the provider, check claims history, and check provider correspondence files for educational/warning letters or contact reports that relate to similar complaints, to help determine whether or not there is a pattern of potential fraud and abuse. The AC or Medicare contractor shall request and review certain documents, as appropriate, from the provider, such as itemized billing statements and other pertinent information. If the AC or Medicare contractor is unable to make a determination on the nature of the complaint (e.g., fraud and abuse, billing errors) based on the aforementioned contacts and documents, the AC or Medicare contractor shall order medical records and limit the number of medical records ordered to only those required to make a determination. If the medical records are not received within 45 business days, the claim(s) shall be denied (if fraud is suspected when medical records are not received, these situations shall be referred to the PSC or Medicare contractor BI). The second-level screening staff shall only perform a billing and document review on medical records to verify and validate that services were rendered. If fraud and abuse is suspected after performing the billing and document review, the medical record shall be forwarded to the PSC (if BI work was transitioned to a PSC) or Medicare contractor BI unit for clinician review. If the AC or Medicare contractor staff determines that the complaint is not a fraud and/or abuse issue, and if the staff discovers that the complaint has other issues (e.g., medical review, enrollment, claims processing), it shall be referred to the appropriate department. In these instances, the AC or Medicare contractor shall also be responsible for acknowledging these complaints, and sending appropriate resolution letters to the beneficiary or complainant. If the AC or Medicare contractor second-level screening staff determines that the complaint is a potential fraud and abuse situation, the second-level screening staff shall forward it to the PSC or Medicare contractor BI unit for further development within 45 business days of the date of receipt from the initial screening staff, or within 30 business days of receiving medical records and/or other documentation, whichever is later. The AC or Medicare contractor shall refer immediate advisements received by beneficiaries or providers and potential fraud or abuse complaints received by current or former provider employees immediately to the PSC or Medicare contractor BI unit for further development.

The AC or Medicare contractor shall be responsible for screening all Harkin Grantees or Senior Medicare Patrol complaints for fraud. If after conducting second level screening, the AC or Medicare contractor staff determines that the complaint is a potential fraud and abuse situation, the complaint shall be sent to the PSC or Medicare contractor BI unit within 45 business days of the date of receipt from the initial screening staff, or within 30 business days of receiving medical records and/or other documentation, whichever is later. The complainant shall be clearly identified to the PSC or Medicare contractor BI unit as a Harkin Grantees or Senior Medicare Patrol complaint. The AC or Medicare contractor shall be responsible for entering all initial referrals identified in the second-level screening area and any updates received from the PSC or Medicare contractor BI unit into the Harkin Grantees Tracking System (HGTS).

The AC or Medicare contractor shall be responsible for downloading and screening complaints from the OIG Hotline Database, and for updating the database with the status of all complaints. If the AC or Medicare contractor determines that the complaint is a potential fraud and abuse situation, the second-level screening staff shall forward it to the PSC or Medicare contractor BI unit for further development within 45 business days of receipt, or within 30 business days of receiving medical records and/or other documentation, whichever is later, just like all other complaints. The PSC or Medicare contractor BI unit shall be responsible for updating the valid cases that have been referred. PSCs and Medicare contractors shall control all OIG Hotline referrals by the OIG Hotline number (the “H” or “L” number) as well as by any numbers used in the tracking system. PSCs and Medicare contractors shall refer to this number in all correspondence to the RO.

Complaints shall be forwarded to the Medicare contractor BI unit or PSC for further investigation under the following circumstances (this is not intended to be an all inclusive list):

Claims forms may have been altered or upcoded to obtain a higher reimbursement amount.

It appears that the provider may have attempted to obtain duplicate reimbursement (e.g., billing both Medicare and the beneficiary for the same service or billing both Medicare and another insurer in an attempt to be paid twice). This does not include routine assignment violations. An example for referral might be that a provider has submitted a claim to Medicare, and then in two days resubmits the same claim in an attempt to bypass the duplicate edits and gain double payment. If the provider does this repeatedly and the AC or Medicare contractor determines this is a pattern, then it shall be referred.

Potential misrepresentation with respect to the nature of the services rendered, charges for the services rendered, identity of the person receiving the services, identity of persons or doctor providing the services, dates of the services, etc.

Alleged submission of claims for non-covered services are misrepresented as covered services, excluding demand bills and those with Advanced Beneficiary Notices (ABNs).

Claims involving potential collusion between a provider and a beneficiary resulting in higher costs or charges to the Medicare program.

Alleged use of another person's Medicare number to obtain medical care.

Alleged alteration of claim history records to generate inappropriate payments.

Alleged use of the adjustment payment process to generate inappropriate payments.

Any other instance that is likely to indicate a potential fraud and abuse situation.

When the above situations occur, and it is determined that the complaint needs to be referred to the PSC or Medicare contractor BI unit for further development, the AC or Medicare contractor shall prepare a referral package that includes, at a minimum, the following:

Provider name, provider number, and address.

Type of provider involved in the allegation and the perpetrator, if an employee of the provider.

Type of service involved in the allegation.

Place of service.

Nature of the allegation(s).

Timeframe of the allegation(s).

Narration of the steps taken and results found during the AC's or Medicare contractor's screening process (discussion of beneficiary contact, if applicable, information determined from reviewing internal data, etc.).

Date of service, procedure code(s).

Beneficiary name, beneficiary HICN, telephone number.

Name and telephone number of the AC or Medicare contractor employee who received the complaint.

NOTE: Since this is not an all-inclusive list, the PSC or Medicare contractor BI unit has the right to request additional information in the resolution of the complaint referral or the subsequent development of a related case (e.g., provider enrollment information).

When a provider inquiry or complaint of potential fraud and abuse or immediate advisement is received, the second-level screening staff will not perform any screening, but will prepare a referral package and send it immediately to the PSC or Medicare contractor BI unit. The referral package shall consist of the following information:

Provider name and address.

Type of provider involved in the allegation and the perpetrator, if an employee of a provider.

Type of service involved in the allegation.

Relationship to the provider (e.g., employee or another provider).

Place of service.

Nature of the allegation(s).

Timeframe of the allegation(s).

Date of service, procedure code(s).

Name and telephone number of the AC or Medicare contractor employee who received the complaint.

The AC and Medicare contractor shall maintain a copy of all referral packages.

The AC or Medicare contractor shall report all costs associated with second-level screening of inquiries for both beneficiaries and providers in Activity Code 13201. Report the total number of second-level screening of beneficiary inquiries that were closed in workload column 1; report the total number of medical records ordered for beneficiary inquiries that were closed in workload column 2; and report the total number of potential fraud and abuse beneficiary complaints identified and referred to the PSC or Medicare contractor BI unit in workload column 3. The AC or Medicare contractor shall keep a record of the cost and workload for all provider inquiries of potential fraud and abuse that are referred to the PSC or Medicare contractor BI unit in Activity Code 13201/01.

B. Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit Responsibilities

At the point the complaint is received from the AC or Medicare contractor screening staff, it shall be the responsibility of the PSC or Medicare contractor BI unit to further investigate the complaint, resolve the complaint investigation, or make referrals as needed to appropriate law enforcement entities or other outside entities.

It shall be the responsibility of the PSC or the Medicare contractor BI unit to send out acknowledgement letters for complaints received from the AC or Medicare contractor. The AC or Medicare contractor shall be responsible for screening and forwarding the complaints within 45 business days from the date of receipt by the second level screening staff, or within 30 business days of receiving medical records and/or other documentation, whichever is later, to the PSC or Medicare contractor BI unit. The PSC or Medicare contractor BI unit shall send the acknowledgement letter within 15 calendar days of receipt of the complaint referral from the AC or Medicare contractor second-level screening staff, unless it can be resolved sooner. The letter shall be sent out on PSC or Medicare contractor BI unit letterhead and shall contain the telephone number of the PSC or Medicare contractor BI unit analyst handling the case.

If the PSC or Medicare contractor BI unit staff determines, after investigation of the complaint, that it is not a fraud and/or abuse issue, but has other issues (e.g., medical review, enrollment, claims processing, etc.), it shall be referred to the AC or Medicare contractor area responsible for second-level screening, or if applicable, the appropriate PSC unit for further action. This shall allow the AC or Medicare contractor screening area to track the complaints returned by the PSC or Medicare contractor BI unit. However, the PSC or Medicare contractor BI unit shall send an acknowledgement to the complainant, but indicate that a referral is being made, if applicable, to the appropriate PSC, or to the appropriate AC or Medicare contractor unit for further action.

The PSC or Medicare contractor BI unit shall be responsible for communicating any updates as a result of their investigation on Harkin Grantees or Senior Medicare Patrol complaints to the AC or Medicare contractor second-level screening staff, who shall update the database accordingly.

The PSC or Medicare contractor BI unit shall be responsible for updating valid cases that have been referred from the OIG Hotline Database by the AC or Medicare contractor second-level screening area.

The PSC or Medicare contractor BI unit shall be responsible for sending the complainant a resolution within 7 calendar days of the resolution on the complaint investigation and/or case in accordance with PIM Chapter 4, §4.8.

4.6.3 -Filing Complaints

(Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units file complaints in the investigation file (refer to the sections below on investigations) that originated from the complaint, and check

each against PSC or Medicare contractor BI unit files for other complaints involving the same provider.

PSCs and Medicare contractor BI units resolve any potential fraud or abuse situations without referral to OIG/OI, if possible, and maintain all documentation on these complaint investigations for subsequent review by CMS personnel or OIG/OI.

A. Source of Complaint

Record the name and telephone number of the individual (or organization) that provided the information concerning the alleged fraud or abuse. Also list the provider's name, address, and ID number.

B. Nature of Complaint

Briefly describe the nature of the alleged fraud or abuse (e.g., “Provider billed for services not furnished,” or “Beneficiary alleged provider billed for more than deductible and coinsurance”).

Also include the following information:

- The date the complaint was received.
- A brief description of the action taken to close out the complaint. For example, “Reviewed records and substantiated amounts billed beneficiary.” Insure that sufficient information is provided to enable the OIFO or the RO to understand the reason for the closeout.
- The date the complaint was closed.
- The number of complaints received to date concerning this provider, including the present complaint. This information is useful in identifying providers that are involved in an undue number of complaints.

4.7 - Investigations

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

An investigation is the analysis performed on both proactive and reactive leads (e.g., complaints, data analysis, newspaper articles) in an effort to substantiate the lead or allegation as a case. However, not all investigations will result in cases.

When PSCs or Medicare contractor BI units receive an allegation of fraud, or identify a potentially fraudulent situation, they shall investigate to determine the facts and the magnitude of the alleged fraud. They shall also conduct a variety of reviews to determine the appropriateness of payments, even when there is no evidence of fraud. Prioritization of the investigation workload is critical to ensure that the resources available are devoted

primarily to high-priority investigations. (Complaints by current or former employees require immediate advisement to the OIG/OI. OIG/OI may request that PSCs or Medicare contractor BI units perform only limited internal investigation and then immediately refer the case to them.)

The PSCs and Medicare contractor BI units shall maintain files on all investigations. The files shall be organized by provider or supplier and shall contain all pertinent documents, e.g., original referral or complaint, investigative findings, reports of telephone contacts, warning letters, documented discussions, any data analysis or analytical work involving the potential subject or target of the investigation, and decision memoranda regarding final disposition of the investigation (refer to §4.2.2.4.2, for retention of these documents).

Under the terms of their contract, PSCs shall investigate potential fraud on the part of providers, suppliers, and other entities who receive reimbursement under the Medicare program for services rendered to beneficiaries. PSCs shall refer potential fraud cases to law enforcement and provide support for these cases. In addition, PSCs may provide data and other information related to potential fraud cases initiated by law enforcement when the cases involve entities or individuals who receive reimbursement under the Medicare program for services rendered to beneficiaries.

The work a PSC performs under its contract does not extend to investigations of ACs and Medicare contractors. PSCs are not authorized to assist a law enforcement agency that may be investigating allegations of fraud or other misconduct against an AC or a Medicare contractor. Requests for assistance of this nature shall be directed to the CMS CO Contractor Compliance Officer, Acquisitions and Grants Group.

4.7.1 – Conducting Investigations

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

When the complaint cannot be dismissed by the AC or Medicare contractor second-level screening staff as an error or a misunderstanding, unless otherwise advised by law enforcement, PSCs and Medicare contractor BI units shall use one or more of the following investigative methods to determine whether or not there is a pattern of submitting false claims. (The list is not intended to be all-inclusive.)

- Review a small sample of claims submitted within recent months. Depending on the nature of the problem, the PSC or Medicare contractor BI unit may need to request medical documentation or other evidence that would validate or cast doubt on the validity of the claims.
- Interview by telephone a small number of beneficiaries. Do not alarm the beneficiaries or imply that the provider did anything wrong. The purpose is to determine whether there appear to be other false claims or if this was a one-time occurrence.

- Look for past contacts by the PSC or the Medicare contractor BI unit, or the MR unit concerning comparable violations. Also, check provider correspondence files for educational/warning letters or for contact reports that relate to similar complaints. Review the complaint file. Discuss suspicions with MR and audit staff, as appropriate.
- Perform data analysis (PSCs shall follow Chapter 2, §2.3 for sources of data).
- Review telephone calls or written questionnaires to physicians, confirming the need for home health services or DME.
- Perform random validation checks of physician licensure.
- Review original CMNs.
- Perform an analysis of high frequency/high cost, high frequency/low cost, low frequency/low cost, and low frequency/high cost procedures and items.
- Perform an analysis of local patterns/trends of practice/billing against national and regional trends, beginning with the top 30 national procedures for focused medical review and other kinds of analysis that help to identify cases of fraudulent billings.
- Initiate other analysis enhancements to authenticate proper payments.
- Perform a compilation of documentation, e.g., medical records or cost reports.

Using internal data, PSCs and Medicare contractor BI units may determine the following:

- Type of provider involved in the allegation and the perpetrator, if an employee of the provider.
- Type of services involved in the allegation.
- Places of service.
- Claims activity (including assigned and non-assigned payment data in the area of the fraud complaint).
- The existence of statistical reports generated for the Provider Audit List (PAL) or other MR reports, to establish if this provider's practice is exceeding the norms established by their peer group (review the provider practice profile).

- Whether there is any documentation available on prior complaints. Obtain the appropriate Form CMS-1490s and/or 1500s, UB-92s, electronic claims and/or attachments. Review all material available.

NOTE: Due to evidentiary requirements, do not write on these forms/documents in any manner.

After reviewing the provider's background, specialty and profile, PSCs and Medicare contractor BI units decide whether the situation, is potential fraud or may be more accurately categorized as a billing error. For example, records indicate that a physician has billed, in some instances, both Medicare and the beneficiary for the same service. Upon review, a PSC or Medicare contractor BI unit determines that, rather than attempting to be paid twice for the same service, the physician made an error in his/her billing methodology. Therefore, this would be considered a determination of improper billing, rather than fraud involving intentional duplicate billing.

The purpose of these activities is to decide whether it is reasonable to spend additional investigative resources. If there appears to be a pattern, the PSC and Medicare contractor BI unit shall discuss it with OIG/OI at the onset of the investigation. The PSC and Medicare contractor BI unit shall discuss with OIG/OI the facts of the investigation and obtain OIG's recommendation on whether or not the investigation should be further developed for possible case referral to OIG/OI.

Once a case has been referred to law enforcement, the PSC and Medicare contractor BI unit shall not contact the provider or their office personnel. If there is belief that provider contact is necessary, the PSC and Medicare contractor BI unit shall consult with OIG/OI. OIG/OI will consider the situation and, if warranted, concur with such contact.

Additionally, if the suspect provider hears that its billings are being reviewed or learns of the complaint and contacts the PSC or the Medicare contractor BI unit, they shall report such contact immediately to OIG/OI.

NOTE: If investigations do not result in a case, the PSC and Medicare contractor BI unit shall take all appropriate action in order to prevent any further payment of inappropriate claims and to recover any overpayments that may have been made (the PSC and Medicare contractor BI unit shall refer to chapter 3, §3.8ff for overpayments).

4.7.2 – Closing Investigations (Rev. 71, 04-09-04)

An investigation shall be closed if it becomes a case (i.e., it is referred to OIG, DOJ, FBI, or AUSA), if it is referred back to the AC or to another PSC due to an incorrect referral or misrouting, or if it is closed with administrative action (refer to §4.11.2.8 for FID instructions on closing investigations).

4.8 - Disposition of Cases

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

A case exists when the PSC or Medicare contractor BI unit has referred a fraud allegation to law enforcement, including but not limited to documented allegations that: a provider, beneficiary, supplier, or other subject a) engaged in a pattern of improper billing, b) submitted improper claims with suspected knowledge of their falsity, or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity. This definition of a case includes any and all allegations (regardless of dollar threshold or subject matter) where PSC or Medicare contractor BI unit staff verify to their own satisfaction that there is potential Medicare fraud (the allegation is likely to be true) and a referral to law enforcement has been performed. PSCs and Medicare contractor BI units do not prove fraud; such action is within the purview of the Department of Justice.

Immediate advisements shall not be considered cases (see PIM Chapter 4, §4.18.1.2).

The PSCs and Medicare contractor BI units shall summarize the case and shall send two copies of the summary report of investigation, with the case file, to OIG/OI. PSCs and Medicare contractor BI units shall ensure that case material is filed in an organized manner (e.g., chronological order, all pages attached with prongs or other binding material, and in the same order as summarized). When necessary, include copies of the claims (with attachments) at issue as well as copies of documentation of all educational/warning contacts with the provider that relate to this issue. See PIM Chapter 4, §4.18.1ff (Referral of Cases to Office of Inspector General/Office of Investigations) for further instruction on referrals to OIG/OI.

There may be instances when law enforcement requests that an investigation be referred before completion of the PSC or Medicare contractor BI unit investigation and case referral package. When this occurs, the PSC and Medicare contractor BI unit shall request law enforcement to send a letter or e-mail requesting immediate referral and acknowledging that the PSC or Medicare contractor BI unit did not complete their investigation and referral package. However, the PSC and Medicare contractor BI unit shall continue their investigation even though an expedited referral has been made to law enforcement in order to determine the appropriate administrative actions.

Once the case has been referred to OIG/OI, inform the complainant within 7 calendar days that the case has been referred to OIG/OI, and that further requests concerning the matter should be referred to OIG/OI. However, some cases may be sensitive and the complainant is not to be informed of the referral to OIG/OI. The PSC and Medicare contractor BI unit shall contact OIG/OI before responding to the complainant if the case is a sensitive one. Otherwise, provide the complainant with the address of OIG/OI and the name of a contact person.

Also, PSCs and Medicare contractor BI units should notify the complainant within 7 calendar days of OIG/OI completing the case. OIG/OI will make a determination as to whether or not the case is to be referred to the FBI or other law enforcement agency for

disposition. If adverse action is subsequently taken against the provider, explain to the complainant the action taken. Thank the complainant for his/her interest and diligence.

4.8.1 – Reversed Denials by Administrative Law Judges on Open Cases (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

If a case is still pending at the OIG, FBI, or AUSA, and denials are reversed by an Administrative Law Judge (ALJ), PSCs and Medicare contractor BI units should recommend to CMS that it consider protesting the ALJ's decision to pay to the DHHS Appeals Council, which has the authority to remand or reverse the ALJ's decision. PSCs and Medicare contractor BI units should be aware, however, that ALJs are bound only by statutory and administrative law (federal regulations), CMS rulings, and National Coverage Determinations.

The New York and Dallas ROs coordinate these protests. Medicare contractor BI units shall consult with their ROs before initiating a protest of an ALJ's decision, and PSCs shall consult with their Primary GTL, Associate GTL, and SME. They should be aware that the Appeals Council has only 60 days in which to decide whether to review an ALJ's decisions. Thus, CMS needs to protest the ALJ decision within 30 days of the decision, to allow the Appeals Council to review within the 60-day limit. PSCs and Medicare contractor BI units shall notify all involved parties immediately if they learn that claims/claim denials have been reversed by an ALJ in a case pending prosecution.

4.9 - Incentive Reward Program (Rev. 71, 04-09-04)

Section 203(b)(1) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) instructs the Secretary to establish a program to encourage individuals to report information on individuals and entities that are engaged in or have engaged in acts or omissions that constitute grounds for the imposition of a sanction under §§1128, 1128A, or 1128B of the Act, or who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act.

The Incentive Reward Program (IRP) was established to pay an incentive reward to individuals who provide information on Medicare fraud and abuse or other sanctionable activities. This rule adds a new Subpart E to 42 CFR 420 ("Program Integrity: Medicare"), which consists of §§420.400 - 420.405. This new Subpart E includes provisions to implement §203(b) of Public Law 104-191 and is entitled "Rewards for Information Relating to Medicare Fraud and Abuse." The final rule was effective on July 8, 1998. The following information is intended as guidance for implementing IRP.

4.9.1 - Incentive Reward Program General Information (Rev. 71, 04-09-04)

The Medicare program will make a monetary reward only for information that leads to a minimum recovery of \$100 of Medicare funds from individuals and entities

determined by the CMS to have committed sanctionable offenses. Referrals from PSCs or Medicare contractor BI units to the OIG made pursuant to the criteria set forth in PIM, chapter 4, §4.19ff are considered sanctionable for the purpose of the IRP.

4.9.2 - Information Eligible for Reward **(Rev. 71, 04-09-04)**

The information must relate to a specific situation, individual, or entity, and must specify the time period of the alleged activities. It must be relevant material information that directly leads to the imposition of a sanction, and non-frivolous. CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS, its PSCs, Medicare contractor BI units, the OIG, the DOJ, the FBI, or any other federal, state or local law enforcement agency.

4.9.3 - Persons Eligible to Receive a Reward **(Rev. 71, 04-09-04)**

The complainant shall be determined to be eligible for a reward only if the initial complaint was received on or after July 8, 1998 and provides information that leads to a sanctionable offense as described in PIM Chapter 4, §4.19ff and Chapter 4, §4.6ff. In general, a reward is payable to all eligible individuals whose complaints were integral to the opening of a BI case. Where multiple complaints have been received, the following guidelines shall be used:

- Only complaints directly relevant to the issue/allegation investigated are eligible.
- In situations where two or more complaints of the same nature concerning the same provider/entity are received, all complaints may be eligible to share an equal portion of the reward not to exceed the maximum amount of the reward.
- The reward shall be paid to the complainant(s) who provided sufficient, specific information to open the case as discussed above.

The PSC or Medicare contractor BI unit shall make a determination of eligibility for a reward as appropriate.

4.9.4 - Excluded Individuals **(Rev. 71, 04-09-04)**

The following individuals are not eligible to receive a reward under the IRP:

- An individual who was, or is, an immediate family member of an officer or employee of the Department of Health and Human Services, its PSCs, ACs, Medicare contractors or subcontractors, the Social Security Administration (SSA), the OIG, a state Medicaid agency, the DOJ, the FBI, or any other federal, state, or

local law enforcement agency at the time he or she came into possession, or divulged information leading to a recovery of Medicare funds. Immediate family is as defined in 42 CFR 411.12(b), which includes any of the following:

- Husband or wife
 - Natural or adoptive parent, child, or sibling
 - Stepparent, stepchild, stepbrother, or stepsister
 - Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law
 - Grandparent or grandchild.
- Any other federal or state employee, PSC, AC, Medicare contractor or subcontractor, or DHHS grantee, if the information submitted came to his/her knowledge during the course of his/her official duties.
 - An individual who received a reward under another government program for the same information furnished.
 - An individual who illegally obtained the information he/she submitted.
 - An individual who participated in the sanctionable offense with respect to which payment would be made.

4.9.5 - Amount and Payment of Reward **(Rev. 71, 04-09-04)**

The amount of the reward shall not exceed 10 percent of the overpayments recovered in the case, or \$1,000, whichever is less. Collected fines and penalties are not included as part of the recovered money for purposes of calculating the reward amount. If multiple complainants are involved in the same case, the reward will be shared equally among each complainant but not to exceed the maximum amount of the reward.

4.9.6 - Program Safeguard Contractor and Medicare Contractor Responsibilities **(Rev. 71, 04-09-04)**

For PSCs and ACs, the IRP responsibilities explained below shall be worked out in the Joint Operating Agreement.

4.9.6.1 - Guidelines for Processing Incoming Complaints **(Rev. 71, 04-09-04)**

On or after **July 8, 1998**, any complaints received that pertain to a potentially sanctionable offense as defined by §§1128, 1128A, or 1128B of the Act, or that pertain to those who have otherwise engaged in sanctionable fraud and abuse against the Medicare program under title XVIII of the Act, are eligible for consideration for reward under the IRP. While the complainant may not specifically request to be included in the IRP, the PSC or Medicare contractor BI unit should consider the complainant for the reward program. Complaints may originate from a variety of sources such as the OIG Hotline, the PSC, the Medicare contractor BI unit, customer service representatives, etc. PSCs, ACs, and Medicare contractors shall inform their staff of this program so they will respond to or refer questions correctly. PIM Exhibit 5 provides IRP background information to assist staff who handle inquiries. PSCs, ACs, and Medicare contractors, shall treat all complaints as legitimate until proven otherwise. They shall refer incoming complaints to the PSC or Medicare contractor BI unit for investigation. Complaints shall either be resolved by the PSC or Medicare contractor BI unit or, if determined to be a sanctionable offense, referred to the OIG for investigation. Complaints that belong in another PSC's or Medicare contractor's jurisdiction shall be recorded and forwarded to the appropriate PSC or Medicare contractor. All information shall be forwarded to them according to existing procedures.

If an individual registers a complaint about a Medicare Managed Care provider, PSCs, ACs, and Medicare contractors shall record and forward all information to:

Centers for Medicare & Medicaid Services
Centers for Medicare Management
Performance Review Division
Mail Stop C4-23-07
7500 Security Blvd.
Baltimore, MD 21244

4.9.6.2 - Guidelines for Incentive Reward Program Complaint Tracking (Rev. 71, 04-09-04)

The PSCs and Medicare contractors shall continue to track all incoming complaints potentially eligible for reward in their existing internal tracking system. The following complainant information shall be included:

- Name;
- Health insurance claim number or Social Security number (for non-beneficiary complaints);
- Address;
- Telephone number; or

- Any other requested identifying information needed to contact the individual.

The PSCs and Medicare contractor BI units shall refer cases to the OIG for investigation if referral criteria are met according to PIM Chapter 4, §4.18.1 - Referral of Cases to the Office of the Inspector General (OIG). The case report shall also be forwarded to the OIG.

The PSC or Medicare contractor BI unit shall enter all available information into the IRP tracking database. Information that shall be maintained on the IRP tracking database includes:

- Date the case is referred to the OIG.
- OIG determination of acceptance.
- If accepted by OIG, the date and final disposition of the case by the OIG (e.g., civil monetary penalty (CMP), exclusion, referral to DOJ).
- Any provider identifying information required in the FID, e.g., the Unique Physician Identification Number (UPIN).

The OIG has 90 calendar days from the referral date to make a determination for disposition of the case. If no action is taken by the OIG within the 90 calendar days, the PSC or Medicare contractor BI unit should begin the process for recovering the overpayment and issuance of the reward, if appropriate.

4.9.6.3 - Overpayment Recovery (Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units shall initiate overpayment recovery actions according to PIM Chapter 3, §3.8ff, if it is determined an overpayment exist. For PSCs, only ACs shall issue demand letters and recoup the overpayment.

4.9.6.4 - Eligibility Notification (Rev. 71, 04-09-04)

After all fraudulently obtained Medicare funds have been recovered and all fines and penalties collected, if appropriate, the PSC or Medicare contractor BI unit will send a reward eligibility notification letter and a reward claim form to the complainant by mail at the most recent address supplied by the individual. PIM Exhibit 5.1 provides a sample eligibility notification letter and Exhibit 5.2 provides a sample reward claim form that may be used as guides.

4.9.6.5 - Incentive Reward Payment (Rev. 71, 04-09-04)

After the complainant has returned the reward claim form with appropriate attachments, the PSC or Medicare contractor BI unit shall determine the amount of the reward and initiate payment. The reward payment should be disbursed to the complainant from the overpayment money recovered. Payments made under this system are considered income and subject to reporting under Internal Revenue Service tax law. No systems changes to implement these procedures are to be made.

For Medicare contractors who have transitioned their BI work to a PSC, only the AC shall make IRP payments. The PSC shall provide the necessary documentation to the AC to initiate the IRP payment.

4.9.6.6 - Reward Payment Audit Trail (Rev. 71, 04-09-04)

The PSC or Medicare contractor BI unit shall maintain an audit trail of the disbursed check. The following data shall be included:

- Amount of the disbursed check
- Date issued
- Check number
- Overpayment amount identified
- Overpayment amount recovered
- Social Security number of complainant
- Party the complaint is against

The PSC or Medicare contractor BI unit shall update the IRP tracking database to reflect disbursement of the reward check to the complainant, and the PSC shall work with the AC via the JOA to disburse the reward check.

4.9.7 - CMS Incentive Reward Winframe Database (Rev. 71, 04-09-04)

The IRP database was designed to track rewards that could be paid for information about fraud or abuse of the Medicare Trust Fund. Access to the IRP database is through the Winframe file server located at the CMS data center and is controlled through password and access codes. Cases can be entered into the IRP system by any PSC, Medicare contractor BI unit, or managed care organization contractor, or by the OIG. When the PSC or Medicare contractor BI unit refers a case to the OIG, for which the complaint is eligible for the IRP, they shall update the IRP system with all available information. The database contains the current status of all Medicare fraud/abuse cases pending reward.

Some cases may be closed without a reward, based on final disposition of the case. PSCs and Medicare contractor BI units and CMS ROs have oversight responsibility for this system. The database provides the following information:

- On-demand management reports
- Duplicate complaints submitted for reward
- Audit trail of overpayments recovered as a result of the reward program

The IRP database user instructions are found in PIM Exhibit 5.3.

4.9.8 - Updating the Incentive Reward Database (Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units shall be responsible for updating the incentive reward database on overpayment recovery and reward amounts. PSCs and Medicare contractor BI units shall regularly follow up with the OIG to obtain information on recovery of complaints referred to them that originated from an IRP complainant. The PSCs and Medicare contractor BI units shall follow up on referrals to the OIG when no action is taken within 90 calendar days. The tracking system database shall be updated as information becomes available. Updates shall be entered, at a minimum, on a quarterly basis.

IRP screens may be viewed in PIM Exhibit 5.9

4.10 - Fraud Alerts (Rev. 71, 04-09-04)

Fraud Alerts are issued when there is a need to advise the PSCs, Carriers, Fiscal Intermediaries, law enforcement, QIOs, and beneficiary communities about an activity that resulted in the filing of inappropriate and potentially false Medicare claims.

The Fraud Alert describes the particular billing, merchandising practice, or activity in enough detail to enable the PSC and Medicare contractor BI unit to determine whether the practice exists in their jurisdiction.

When one of these Fraud Alerts is received, the PSC or Medicare contractor BI unit shall determine whether the scheme exists within their jurisdiction. If it does, PSCs and Medicare contractor BI units shall take appropriate action to protect the Medicare Trust Fund. Action may include denials, suspensions, overpayment recovery, and/or conducting of an investigation for case referral to OIG. In each case, the action the PSC or Medicare contractor BI unit takes shall be based on findings developed independently of the Alert. Once the Alert has been investigated, the results of the investigation shall be reported to the CMS RO SME (i.e., whether the scheme exists in the PSC's or Medicare contractor BI unit's jurisdiction) and the steps that were taken to safeguard the Medicare

Trust Fund.

4.10.1 - Types of Fraud Alerts

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Below are the various types of Fraud Alerts that are issued:

A. National Medicare Fraud Alert

The most commonly issued Fraud Alert is the National Medicare Fraud Alert (NMFA). (See PIM Exhibit 27 for the NMFA template). NMFAs do not identify specific providers or other entities suspected of committing fraud. They focus on a particular scheme or scam and are intended to serve as a fraud detection lead.

The CO issues an NMFA when a fraudulent or abusive activity is perceived to be, or has the potential for being widespread, i.e., crossing PSC or Medicare contractor BI unit jurisdictions. These Alerts are numbered sequentially. Because CMS and OIG use a comparable numbering system, CMS National Medicare Fraud Alerts are identified as “CMS NMFA,” followed by the Alert number appearing in the bottom left-hand corner. OIG Alerts are identified by “OIG,” followed by the Alert number appearing in parenthesis in the bottom left-hand corner. The National Medicare Fraud Alert shall be put on the blue CMS fraud stationery. Medicare contractor BI units and PSCs shall distribute Alerts to all agencies in their jurisdiction within 15 working days of receipt by the PSC or Medicare contractor BI unit.

Draft National Medicare Fraud Alerts to CO shall be password protected and e-mailed to the CMS CO Director of the Division of Benefit Integrity Management Operations.

An NMFA shall contain the two following disclaimers, in bold print:

Distribution of this Fraud Alert is Limited to the Following Audience:

Regional offices, Medicare Contractor Benefit Integrity units, program safeguard contractors, Medicare Integrity Program units, quality improvement organizations, Medicaid Fraud Control units, the Office of Inspector General, the Defense Criminal Investigation Service, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney offices, U.S. Postal Inspectors, the Internal Revenue Service, State surveyors, State Attorneys General, and the State Medicaid program integrity directors.

This Alert is provided for educational and informational purposes only. It is intended to assist interested parties in obtaining additional information concerning potential fraud and to alert affected parties to the nature of the suspected fraud. It is not intended to be used as a basis for denial of claims or any adverse action against any provider or supplier. Such decisions must be made based on facts developed independent of this Alert.

The NMFA does not include a sanitized version, because it does not identify specific providers or entities. The sharing of NMFAs with individuals or groups that are not on the approved distribution list will be left to the discretion of the Medicare contractor BI units and/or PSCs. However, if the Medicare contractor BI units or PSCs choose to share the NMFAs beyond the approved list, the discovery and detection methodology sections shall not be included. These sections shall be disclosed only to the entities appearing on the audience line of the Fraud Alert.

B. Restricted Medicare Fraud Alert

The CMS issues an RMFA when specific providers are identified as being suspected of engaging in fraudulent or abusive practices or activities. PSCs and Medicare contractor BI units prepare this type of Alert (see PIM Exhibit 28 for the RMFA template) when advising other Medicare carriers, intermediaries, PSCs, QIOs, MFCUs, OIG, DCIS, FBI, or DOJ of a particular provider or providers suspected of fraud. These Alerts are numbered sequentially. Because CMS and OIG use a comparable numbering system, CMS Restricted Medicare Fraud Alerts are identified by “CMS RMFA,” followed by the Alert number appearing in the bottom left-hand corner. Distribution is limited to PSCs, Medicare contractors, CMS, QIOs, OIG/OI, DCIS, FBI, MFCUs, U.S. Postal Service, IRS, and the Offices of the U.S. Attorney. The CO will issue each Medicare contractor BI unit and PSC one copy of an RMFA along with a sanitized version. Each Medicare contractor BI unit and PSC shall distribute said Alert to the agencies in their jurisdiction for reproduction on the red CMS fraud stationery within 15 working days of receipt by the PSC or Medicare contractor BI unit.

Draft restricted Medicare Fraud Alerts shall be e-mailed password protected via the secure e-mail system. If problems occur with the secure e-mail system, RMFAs shall be mailed to the following address:

Centers for Medicare & Medicaid Services
OFM/PIG/DBIMO
Mail Stop C3-02-16
7500 Security Blvd.
Baltimore, MD 21244
Attention: Fraud Alert Lead

The envelope shall be marked “personal and confidential” and “do not open in mailroom.” All RMFAs shall be password protected when mailed on diskette or CD-ROM. The content of this Alert is not disclosable to the public even under the Freedom of Information Act. Public disclosure of information protected by the Privacy Act has serious legal consequences for the disclosing individual. It is intended solely for the use of those parties appearing on the audience line. It contains the names and other identifying information of provider or suppliers who are suspected of fraud.

A restricted Medicare Fraud Alert shall contain the following disclaimer exactly as below:

THIS ALERT IS CONFIDENTIAL. It is not intended to be used as a basis for the denial of any claim or adverse action against any provider. Such decisions must be based on facts independent of this Alert.

Distribution is limited to the following audience:

Regional offices, Medicare Contractor Benefit Integrity units, program safeguard contractors, quality improvement organizations, Medicaid Fraud Control units, the Office of the Inspector General, the Defense Criminal Investigation Service, the Department of Justice, the Federal Bureau of Investigation, U.S. Attorney offices, U.S. Postal Inspector offices, the Internal Revenue Service, and the State Medicaid Program Integrity Directors.

NOTE: The RMFAs will be distributed to Medicare Integrity Program units on a need to know basis.

C. CMS Central Office Alert

The PSCs and Medicare contractor BI units shall prepare a CO Alert when:

- The PSCs or Medicare contractor BI units need to notify CMS of a scheme that is about to be publicized on the national media
- The case involves patient abuse or a large dollar amount (approximately \$1 million or more or potential for widespread abuse), or
- The issues involved are politically sensitive, e.g., congressional hearings are planned to accept testimony on a fraudulent or abusive practice

The Alert shall be prepared and submitted in the same manner as a NMFA but the audience line reads “CO Only.” This Alert shall be addressed to: the CMS CO Division of Benefit Integrity Management Operations (DBIMO) Director, the CO PIG Director, the CO PIG Deputy Director, and the CO Fraud Alert Lead.

D. Program Safeguard Contractor or Medicare Contractor BI Unit Alert

- Initially, this Alert generally is sent to the CO as a draft NMFA or RMFA.
- If CMS reviews the Alert and determines that it does not meet the NMFA or RMFA criteria, CMS will deny clearance and issuance.
- The CMS notifies the PSC or Medicare contractor BI unit of the Alert denial.
- If the PSC and Medicare contractor BI unit do not provide CMS with any additional information to justify reconsideration, the denial is final. However, the

PSC and Medicare Contractor BI Unit may issue denied Alerts as PSC/Medicare contractor BI unit Alerts.

- The PSC and contractor BI unit shall provide the CO Fraud Alert lead with a copy of this Alert.

E. Waiver Alerts

On occasion, the OIG waives Medicare exclusions imposed on healthcare providers. Generally, the waiver is granted if the provider is the sole community physician or sole source of essential specialized services in the community.

The CMS' Program Integrity Group will be notified by the OIG of these waivers. Upon receipt of this notification, CMS will issue a Waiver Alert to all PSCs and Medicare contractor BI units. The alert will include a copy of the OIG letter granting the waiver to the provider. The OIG letter may include exceptions to the waiver (e.g., the provider's waiver is limited to certain localities).

Upon receipt of the Waiver Alert, PSCs and Medicare contractor BI units shall provide this information to their respective ACs or Medicare contractor unit to ensure that Medicare payments are not denied inappropriately.

Additionally, CMS will post a remark to the Medicare Exclusion Database (MED) indicating that a Waiver Alert has been issued. PSCs and Medicare contractor BI units shall also monitor the MED for consistency.

4.10.2 - Alert Specifications

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

All Alerts drafted shall meet the following criteria:

- The Alert shall be entitled "National Medicare Fraud Alert," "Restricted Medicare Fraud Alert," "CMS CO Alert," or "PSC or Medicare Contractor BI unit Alert."
- It shall include an audience line that indicates the audience that needs to be made aware.
- It shall have a subject line that briefly describes the issue or subject of the Alert, including the provider's UPIN, Tax ID number, and FID case number (if applicable).
- It shall include the source of the information that defines the alleged improper/suspect behavior (e.g., PIM, Medicare Carrier Manual (MCM), Medicare Intermediary Manual (MIM) section, National Coverage Determinations (NCD), LMRP, etc.).

- The body of the Alert shall describe the matter in enough detail to enable readers to determine their susceptibility to the activity and what they need to do to protect themselves. It includes diagnosis, Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes, the dollar amount involved, the states affected, and applicable policy references, as appropriate.
- It shall include a discovery line that indicates how the PSC or Medicare contractor BI unit who initiated the Alert discovered the problem. (See note below.) This shall be a clear, detailed explanation that will enable others to determine what to look for in their systems. If a previous Fraud Alert was issued addressing a similar situation, it shall include the Fraud Alert reference.
- It shall include a detection methodology detailing the steps or approaches other PSCs or Medicare contractor BI units can use to determine whether this practice is occurring in their jurisdiction (see note below), including the reports run, the edits used, and the timeframes followed.
- It shall include a status that details the current position of the case (e.g., with OIG or FBI, overpayment identified and amount, etc.).
- It shall include the name and telephone number of a person or organization to be contacted in the event of a complaint or question.
- It shall contain the appropriate disclaimer, depending on the type of Alert. CMS CO Alerts and PSC/Medicare contractor BI unit Alerts do not need a disclaimer.

NOTE: Do not include the “discovery” and “detection methodology” sections when distributing an Alert to a provider professional organization or other outside group. These sections are disclosable only to ROs, PSCs, Medicare contractors, and federal law enforcement agencies. Restricted Alerts shall not be distributed beyond the approved distribution list.

4.10.3 - Editorial Requirements

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

The PSCs and Medicare contractor BI units shall adhere to the following requirements when drafting a Fraud Alert:

- Avoid an emotional writing style such as frequent exclamation points, underlining, and bold type. State the issue in as matter-of-fact a way as possible.
- Avoid generalizing the problem to groups, specialties, or types of providers. Focus on the billing practice or issue.

- Do not state that performance of the activity is fraud, even if the practice does violate Medicare requirements. Couch the message in terms of “alleged,” “suspected,” “potential,” and “possible,” fraud, or say it “may be fraud.”
- When stating applicable penalties, use “may” (e.g., “may result in exclusion from the Medicare and Medicaid programs”). Do not state that certain penalties will be applied.
- Avoid programmatic jargon or unnecessary terms of art. Use plain English, whenever possible, while remaining technically accurate. If technical terms are necessary, explain them.

Be certain the Alert is technically accurate, and review it prior to submitting a proposed Alert to CMS CO for publication. Consult with RO and OIG, as necessary. Do not sacrifice technical accuracy in the interest of a speedy issuance or writing in plain English.

Issue portions of Alerts in Spanish or other appropriate foreign language if there is a non-English-speaking population that is potentially affected by the scheme, and there are plans to distribute the Alert to such groups.

4.10.4 - Coordination

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Before preparing an Alert, the PSC or Medicare contractor BI unit shall consult with the applicable RO and/or, PSC network, Primary GTL, Associate GTL, SME, and Medicare contractor BI unit manager. The PSC or Medicare contractor BI unit shall determine whether or not a similar Alert has been issued by contacting PSCs or Medicare contractor BI units in contiguous jurisdictions. If so, that Alert shall be used and the name and address of your organization shall be added to the contact section. The PSC and Medicare contractor BI unit shall forward the draft to CMS Program Integrity Group or the Primary GTL, Associate GTL, and SME (if a PSC) for review and clearance. The Program Integrity Group reviews the draft, acknowledges the Alert, and notifies the PSC or Medicare contractor BI unit whether:

- A National Medicare Fraud Alert will be issued
- A Restricted Medicare Fraud Alert will be issued, or
- The Alert should be issued as a PSC or Medicare contractor BI unit Alert

The CO keeps the PSC or Medicare contractor BI unit informed of the progress of the Alert throughout the clearance process.

4.10.5 - Distribution of Alerts

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

The CMS issues the Alert to the PSCs or Medicare contractor BI units for further distribution. Approved NMFAs are sent through the electronic mail system (password protected) and approved RMFAs are mailed (password protected diskette, CD ROM). Upon receipt of an approved Alert, the PSC or Medicare contractor BI unit shall add their name and telephone number to the existing contact information on the Alert. They shall then reproduce the Alert on their own supply of CMS approved stationery. PSCs or Medicare contractor BI units shall distribute the Alert to the entities that appear on the audience line.

4.11 – Fraud Investigation Database Entries **(Rev. 71, 04-09-04)**

The Fraud Investigation Database (FID) is a nationwide database of Medicare fraud and abuse investigations, cases, and payment suspensions by the PSC or Medicare contractor BI unit.

The following agencies/organizations currently have access to the FID:

- Medicare Program Safeguard Contractors
- Medicare Contractor Benefit Integrity units that have not transitioned to a PSC
- Medicare Contractor Provider Enrollment units
- CMS
- FBI
- DOJ
- DHHS/OIG
- Medicaid Program Integrity Directors, SURs (State Utilization Review) officials, and Provider Enrollment units
- Medicaid Fraud Control Units
- Other federal and state partners seeking to address program integrity concerns in judicial or state health care programs

4.11.1 - Background

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

The FID shall capture information on investigations that have been initiated by the PSC or Medicare contractor BI unit and on cases that have been referred to law enforcement by the PSC or Medicare contractor BI unit. The FID shall also capture information on payment suspensions that have been imposed.

Investigations initiated by the PSC or Medicare contractor BI unit shall be saved in the FID, and contain identifying information on the potential subject of a case.

Cases initiated by the PSC or Medicare contractor BI unit shall contain a summary of the pertinent information on the case referral. At a minimum, the following data shall be included in the case:

- Subject of the case (e.g., physician, hospital, skilled nursing facility, home health agency, comprehensive outpatient rehabilitation facility, etc.).
- Allegation information/nature of the scheme.
- Status of the case.
- Disposition of a case (e.g., administrative action, prosecution, exclusion, settlement, etc.).
- Contact information for PSC, Medicare contractor BI unit, and/or law enforcement.

Payment suspensions shall contain a summary of the pertinent information on the suspension, including date implemented, rebuttal information, and amounts in suspense.

The FID also has monitoring and reporting capabilities, and contains Medicare Fraud Alerts and a Resource Guide, by state, of contacts at PSCs, Medicare contractor BI units, Medicaid Program Integrity Directors and Medicaid Fraud Control Units, and law enforcement agencies.

4.11.1.1 - Information Not Captured in the FID

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

Individual complaints (statements alleging improper entitlement), simple overpayment recoveries (not involving potential fraud), complaints that are returned to the AC or the Medicare contractor second-level screening staff (or PSC, if applicable), and medical review abuses shall not be captured in the FID.

4.11.1.2 - Entering OIG Immediate Advisements into the FID

(Rev. 71, 04-09-04)

All available information shall be entered into the FID, as an investigation, concurrent with, or within 15 calendar days after, the “immediate advisement” and shall be converted to a case if the OIG accepts it.

4.11.2 – Investigation, Case, and Suspension Entries **(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)**

It is not appropriate for an OIG or FBI agent, DOJ, or an Assistant United States Attorney (AUSA), to request that a PSC or Medicare contractor BI unit not enter or update an investigation, case, or payment suspension initiated by the PSC or Medicare contractor BI unit in the FID, except in rare circumstances. PSCs and Medicare contractor BI units shall inform law enforcement agents making such requests that they are required by CMS to maintain the FID and that they do not have the discretion to do otherwise. The PSC or Medicare contractor BI unit shall contact the Primary GTL, Associate GTL, and SME (if a PSC) or RO employee (if a Medicare contractor BI unit) in order to resolve the matter.

However, information regarding law enforcement activities that are, or could be considered to be, of a sensitive nature, including but not limited to, planned search warrants, undercover operations and activities, and executed search warrants, where only some of the search warrants have been executed, shall not be entered into the FID.

4.11.2.1 - Initial Entry Requirements for Investigations **(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)**

Investigations shall capture information on ongoing work in the PSC or Medicare contractor BI unit. For PSCs, investigations are entered when they are reported on the PSC's ART report. For Medicare contractor BI units, investigations are entered when they are being worked in the BI unit, regardless of level of effort, but have not been referred to law enforcement as a case.

Investigations initiated by the PSC or Medicare contractor BI unit shall be entered into the FID within 15 calendar days of the start of the investigation (Investigations are defined in PIM Chapter 4, §4.7). Such investigations shall be saved in the FID and shall not be converted to a case until and unless the investigation results in a referral as a case to the OIG or other law enforcement agency. When an investigation is saved, the FID will assign it an investigation number, starting with the letter N. Any complaints that are returned to the AC or the Medicare contractor second-level screening staff (or PSC, if applicable) shall not be entered into the FID. Such complaints are returned because they pertain to issues other than fraud and abuse.

The minimum initial data entry requirements into the FID for an Investigation shall be (by Tab):

SUBJECT INFORMATION Tab:

- Subject's Name
- Subject's Address (City, State, and Zip Code)

- Subject Type and Subtype

CASE INFORMATION Tab:

- Allegation
- Allegation Source
- Dates of Services (if known)

ACTIONS Tab:

- Actions Taken by: Contractor
- Action Date: [enter the date the investigation was opened]
- Action Narrative: [enter brief statement on the investigation]
- Action: Under Investigation (for PSC or Medicare contractor BI unit initiated investigations)

CONTACTS Tab:

[Confirm contact information is accurate]

There are no mandatory update requirements for investigations, but the PSC and Medicare contractor BI unit shall enter updates as necessary. Should the PSC or Medicare contractor BI unit add information during the investigation phase, it shall still be saved in FID as an investigation.

4.11.2.2 – Initial Entry Requirements for Cases
(Rev. 71, 04-09-04)

Once the PSC or Medicare contractor BI unit has referred a case to the OIG or other law enforcement agency, the investigation shall then be saved as a Case within 15 days of referral. The investigation actually converts to a FID case.

4.11.2.3 – Initial Entry Requirements for Payment Suspension
(Rev. 71, 04-09-04)

For payment suspensions, the information shall be entered into the FID Suspension Module no later than the effective date of the suspension.

4.11.2.4 – Update Requirements for Investigations
(Rev. 71, 04-09-04)

There are no mandatory update requirements for investigations, but the PSC and Medicare contractor BI unit shall enter updates as necessary. Should the PSC or Medicare contractor BI unit add information during the investigation phase, it shall still be saved in FID as an investigation.

4.11.2.5 - Update Requirements for Cases

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

For cases referred to the OIG, the FBI, or other law enforcement agency, updates to the FID case shall be made at least every 3 months (1 month is a maximum of 31 days). If problems are encountered which undermine the PSCs' or Medicare contractor BI units' ability to get updated information, this shall be discussed with the appropriate Primary GTL, Associate GTL, and SME (if a PSC) or RO employee (if a Medicare contractor BI unit).

As applicable, the following tabs/sections shall be updated:

- Referrals accepted by OIG or FBI are assigned a case number by the OIG or FBI. It shall be the responsibility of the PSC or Medicare contractor BI unit to obtain and enter the case number into the FID Case Information tab;
- The Case Narrative section in the FID Case Information tab shall clearly identify the alleged fraudulent activity, all investigation actions, and referral activities performed on the case by the PSC or Medicare contractor BI unit. The sooner comprehensive case information is entered into FID, the more efficiently other PSCs, Medicare contractors, CMS, Medicaid, and law enforcement agencies can react to the case and perform related trend-data analysis;
- The PSC or Medicare contractor BI unit shall enter updated summary information in the FID Actions tab after the case is referred to the OIG/FBI. The status of the case and, when appropriate, actions taken by law enforcement shall be entered into the FID. If the PSC or Medicare contractor BI unit is not able to obtain status on cases referred to and accepted by law enforcement, this shall be brought to the attention of the appropriate Primary GTL, Associate GTL, and SME (if a PSC) or RO employee (if a Medicare contractor BI unit). All corrective and/or administrative actions taken by the AC, PSC, or Medicare contractor shall be entered into the FID;
- Contact with the FBI or an AUSA regarding their actions on a case;
- Capturing and documenting subsequent law enforcement referrals (e.g., OIG declines case, PSC or Medicare contractor BI unit refers case to FBI, FBI accepts case);
- Keeping apprised of MR/provider audit and reimbursement actions if they are taking actions on a case;

- Updating the amount being withheld, denied, or paid;
- Entering information on convictions/sentences; and/or,
- Adding to the case narrative section in the Case Information tab, to incorporate any updated information summarized in the Actions tab.

It is extremely important to document in the FID any consultations with law enforcement as well as administrative actions and associated monetary assessments by the PSC, Medicare contractor BI unit, or law enforcement. PSCs and Medicare contractor BI units shall be responsible for providing such documentation.

4.11.2.6 – Update Requirements for Payment Suspensions (Rev. 71, 04-09-04)

The first update following initial entry of the suspension shall be made within one month; the second update shall be made within two months. Thereafter, the amount being withheld and other pertinent information on the suspension shall be updated in the suspension module every two months, until the suspension is removed. For suspensions under unlimited extension, updates shall be made every three months. (For all references to a month in this section, one month is a maximum of 31 days.)

4.11.2.7 - OIG Non-Response to or Declination of Case Referral (Rev. 71, 04-09-04)

As per instructions found in PIM, Chapter 4, §4.18.1, if the PSC or Medicare contractor BI unit does not hear back from the OIG within the first 90 days following referral, and if repeated attempts by the PSC or Medicare contractor BI unit to find out the status of the case are unsuccessful, the PSC or Medicare contractor BI unit shall then refer the case first to the FBI and if FBI declines the case to any other law enforcement agency with interest in the case. If this subsequent referral to the FBI or any other investigative agency is not acted upon within 45 days, the PSC or Medicare contractor BI unit shall follow up with the FBI or other investigative agency. Subsequent to follow-up, the PSC or Medicare contractor BI unit may close the case in the FID if it is still not acted upon by the FBI or other law enforcement agency, but shall continue to enter any actions that it takes, including administrative actions. For FID tracking purposes, the PSC and Medicare contractor BI unit shall make any additional entries, based upon administrative or other actions taken, or, in the alternative, shall reopen the same FID case at some future time if the OIG, FBI, or other law enforcement agency accepts the case.

If the OIG formally declines a referral and does not itself refer the case to the FBI, the PSC or Medicare contractor BI unit shall refer the case first to the FBI and then to another law enforcement agency if the FBI declines the case. However, when a case is referred to FBI in this situation, it shall be considered an update to the existing FID case, reflecting a subsequent action taken on the case, and not a new FID case. That is, subsequent referrals of the same case to other law enforcement agencies shall not be

counted as new case entries in the FID, nor are they counted for workload purposes as new referrals to law enforcement.

4.11.2.8 – Closing Investigations

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Investigations shall be closed when they are no longer reported as an investigation on CMS analysis, reporting and tracking (ART) or the Medicare contractor BI unit has determined that it will not result in a case (refer to §4.7.2 for a definition of when to close an investigation). The investigation that does not result in referral of a case shall be closed by entering the following action in the ACTIONS Tab in order to indicate that the investigation has been closed:

ACTIONS Tab:

- Action Taken by: Contractor

- Action: Investigation Closed

The PSC or Medicare contractor BI unit shall also enter administrative actions, if any, it has taken as part of disposition of the investigation.

4.11.2.9 – Closing Cases

(Rev. 144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

An active FID case shall be closed when *no further action will be required of the PSC or Medicare contractor BI unit by law enforcement agency(ies) working the case and when the law enforcement agency(ies) has ended all its activity on the case; and when all necessary administrative actions have been finalized (i.e., when the calculated overpayment has been referred to the AC for recoupment). Note that after a case is closed, it can still be updated to reflect any additional activity that takes place (i.e., recoupment of the overpayment by the AC).*

4.11.2.10 – Closing Payment Suspensions

(Rev. 71, 04-09-04)

When the payment suspension is removed, this information shall be entered into the payment suspension module within 15 calendar days of removal. This changes the status of the suspension from Active to Removed. Even after a suspension becomes inactive, updated information on the Actual Overpayment Amount, Amount Recovered, and other pertinent information shall be entered as it becomes available.

4.11.2.11 - Duplicate Investigations, Cases, or Suspensions

(Rev. 71, 04-09-04)

A duplicate investigation, case, or suspension exists when any given PSC or Medicare contractor BI unit inadvertently enters a provider, supplier, or beneficiary as the subject of an investigation, case, or payment suspension more than once, absent different allegations or other differentiating criteria requiring a separate investigation, case, or suspension entry.

For investigations, cases, and suspensions, it shall not be considered a duplicate investigation, case, or suspension if multiple PSCs or Medicare contractor BI units enter investigations, cases, or suspensions for the same provider as the subject of an investigation, case, or suspension. These investigations, cases, and suspensions, however, shall reflect a coordinated effort by all PSCs and Medicare contractor BI units involved and investigating the provider. Case numbers shall be referenced in the Subject Information tab, Related FID Case No. field, and the case description summaries shall reflect this coordination. The FID now has the capability of cross-checking for related cases.

If a new investigation or case is initiated on a provider that was already the subject of a closed investigation or case, a new investigation or case shall be opened. The closed investigation or case, however, shall be mentioned in the Case Narrative screen in the Case Information Tab and cross-referenced to the old investigation or FID case number.

The target, whether entity or individual, shall be entered as the subject of the investigation or case. Any and all related providers, suppliers, beneficiaries, etc., who are in any way affiliated with the subject of the case, shall be identified under “AKAs, DBAs, and Affiliates.” However, if these individuals are the primary subjects/targets of the investigation or case and independent investigations or cases are made against them, then individual investigations or cases shall be established in the FID.

If a new payment suspension has been imposed on a provider that was already the subject of an earlier payment suspension, a new payment suspension shall be entered into the FID. The prior (now inactive) suspension, however, shall be cross-referenced in the Contacts/Narrative Information tab - Suspension Narrative section.

The PSCs and Medicare contractor BI units shall check for potential duplicate entries of investigations, cases, or suspensions.

4.11.2.12 – Deleting Investigations, Cases, or Suspensions **(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)**

Investigations, cases, or suspensions can be deleted from the FID only by users with the “File Manager” (system administrator) designation. As applicable and necessary, the Primary GTL, Associate GTL, and SME or CMS RO will contact and discuss with the PSC or Medicare contractor BI unit the need to correct and/or delete an investigation, a case, or suspension from the database. In the event that a PSC or Medicare contractor decides that an investigation, a case, or suspension should be deleted from the FID, the

investigation number, case number, or suspension number shall be forwarded to the FID mailbox at FID@cms.hhs.gov.

4.11.3 - Operational Issues

(Rev. 71, 04-09-04)

4.11.3.1 - Access

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

If PSCs, Medicare contractor BI units, and others eligible to access the FID have never applied for access to the FID system and require authorization, an “Application for Access to CMS Computer Systems” shall be completed, submitted, and approved.

This form may be acquired from <http://www.cms.hhs.gov/mdcn/access.pdf>. It shall be submitted to the appropriate RACF (Resource Access Control Facility) Group Administrator for all CMS central and regional offices, Medicare contractor BI unit users, or to the CO Primary GTL for PSCs or to the CMS Division of Benefit Integrity Management Operations for all law enforcement personnel or other users.

The CMS Remote Access Guide can be found at the following website:

<http://www.cms.hhs.gov/mdcn/cmsremoteaccessguide.pdf>.

For those individuals who have received prior authorization, but are experiencing authorization lapses or password problems, the same contacts referenced above shall be contacted. Internet access problems shall be directed to the CMS IT Service Desk, at (410) 786-2580 or 1-800-562-1963.

4.11.3.2 - The Fraud Investigation Database User’s Group

(Rev. 71, 04-09-04)

Membership in the FID User’s Group is voluntary and open to all Users. The group discusses proposed enhancements, upgrades, current issues, matters of interest to users, etc. Anyone interested in joining the group can send an email to the FID mailbox:

FID@cms.hhs.gov

Notice of programming changes in the FID (e.g., enhancements, upgrades, changes to entry requirements) shall be issued by the FID User’s Group, and disseminated as widely as possible. PSCs and Medicare contractor BI units shall refer to FID User’s Group minutes for entry instructions. Programming changes are also communicated via News Items posted in the FID.

4.11.3.3 – Designated PSC and Medicare Contractor BI Unit Staff and the Fraud Investigation Database

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

The designated PSC and Medicare contractor BI unit staff receive training on how to input and maintain cases in the FID. The intent is to use these staff members as FID experts and points of contact for questions and comments on the FID. They shall be responsive to FID questions from PSCs and Medicare contractor BI units and law enforcement personnel within their jurisdiction.

Designated PSC and Medicare contractor BI unit staff shall serve as a resource to CMS on the FID, including FID training.

Designated staff at each PSC and Medicare contractor BI unit shall be responsible for sharing FID information and analysis (e.g., FID system reports) with the PSC and Medicare contractor BI manager and BI staff. If the designated PSC and Medicare contractor BI unit staff detects any inaccuracies or discrepancies in cases entered by their PSC or Medicare contractor BI unit, they shall notify the PSC or Medicare contractor BI manager.

4.11.3.4 - The Fraud Investigation Database Mailbox (Rev. 71, 04-09-04)

Anyone can send an email to the FID mailbox with a question, comment, or suggestion about the FID. The address is FID@cms.hhs.gov

4.12 - Harkin Grantees or Senior Medicare Patrol - Complaint Tracking System (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

This section provides instructions for implementing the Harkin Grantees Tracking System (HGTS).

4.12.1 - Harkin Grantees or Senior Medicare Patrol Project Description (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The Harkin Grantees or Senior Medicare Patrol (named after Senator Tom Harkin) are part of a broad initiative to combat waste, fraud, and abuse within the Medicare program. The anti-abuse initiative is supported by the partnership between the Department of Health and Human Services, Office of Inspector General, and the Administration on Aging (AOA).

The Harkin Grantees or Senior Medicare Patrol are senior volunteers who focus on detecting and reporting fraudulent or improper Medicare activities, primarily in home health care, nursing facilities, hospice, and durable medical equipment suppliers.

4.12.2 - Harkin Grantee Tracking System Instructions (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The AC or Medicare contractor second-level screening staff shall be responsible for collecting, tracking, and reporting the administrative and monetary results of fraud and abuse complaints generated by the Harkin Grantees or Senior Medicare Patrol state projects, including those complaints referred to the PSC or Medicare contractor BI unit. The AC or Medicare contractor second-level screening staff shall develop aggregate reports available to the Harkin Grantees or Senior Medicare Patrol state project coordinators every 6 months.

The Harkin Grantees or Senior Medicare Patrol State/local contact information is available at <http://www.aoa.gov/smp/index.asp>

4.12.3 - System Access to Metaframe and Data Collection (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The Harkin Grantees Tracking System migrated from the Winframe to the Metaframe server. Access the Metaframe system as follows:

Download the new Citrix Client and upgrade. Download the Client software:
<http://download2.citrix.com/files/en/products/client/ica/current/ica32.exe>

Each AC and Medicare contractor shall designate a person in the second-level screening staff to input the complaint into the HGTS database located on the Metaframe system. These designees shall enter data on a continuous basis related to complaints generated by the Harkin Grantees or Senior Medicare Patrol state projects.

The Harkin Grantees or Senior Medicare Patrol will report their complaints according to their usual procedure, using the model complaint form (PIM Exhibit 32).

Upon receiving Harkin Grantees or Senior Medicare Patrol complaints, the AC or Medicare contractor second-level screening staff shall enter the following information into the Metaframe database fields.

- Project number
- Date of Report
- Provider Number
- Provider Name
- Provider City
- Provider State
- AC or Medicare Contractor Number

- Overpayment Identified
- Overpayment Recovered
- Action Taken
- Further Explanation

If the PSC or Medicare contractor BI unit completes the complaint review, they shall provide the above information, as applicable, to the AC or Medicare contractor second-level screening staff for input.

4.12.4 - Data Dissemination/Aggregate Report (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The AC or Medicare contractor second-level screening staff shall compile information in the database into an aggregate report. The AC or Medicare contractor shall distribute the aggregate report to the Harkin Grantees or Senior Medicare Patrol state project coordinators every 6 months. Aggregate reports shall be distributed by the second week of July (covering January - June data) and the second week of January (covering July - December data).

The January through June/July through December report cycle shall be continuous until further instruction.

The AC and Medicare contractors second-level screening staff shall forward copies of the aggregate reports to the CMS CO Director of the Division of Benefit Integrity Management Operations.

4.13 - Administrative Relief from Benefit Integrity Review in the Presence of a Disaster (Rev. 71, 04-09-04)

During a disaster, whether man-made or natural, the PSC and Medicare contractor BI unit shall continue every effort to identify cases of potential fraud. Therefore, if the PSC or Medicare contractor BI unit suspects fraud of a provider who cannot furnish medical records in a timely manner due to a disaster, the PSC or Medicare contractor BI unit shall ensure that the provider is not attempting to harm the Medicare Trust Fund by taking 6 months or more to furnish medical records. As such, the PSC or Medicare contractor BI unit shall request and review verification documentation in all instances where fraud is suspected.

In the case of complete destruction of medical records/documentations where backup records exist, PSCs or Medicare contractor BI units shall accept reproduced medical records from microfiched, microfilmed, or optical disk systems that may be available in larger facilities, in lieu of the original document. In the case of complete destruction of medical records where no backup records exist, PSCs or Medicare contractor BI units

shall instruct providers to reconstruct the records as best they can with whatever original records can be salvaged. Providers should note on the face sheet of the completely or partially reconstructed medical record: "This record was reconstructed because of disaster."

4.14 - Provider Contacts by the Program Safeguard Contractor and Medicare Contractor Benefit Integrity Unit **(Rev. 71, 04-09-04)**

A PSC or Medicare contractor BI unit may determine that the resolution of an investigation does not warrant referral for criminal, CMP, or sanction, and that an educational meeting with the provider is more appropriate. The PSC or Medicare contractor BI unit shall inform the provider of the questionable or improper practices, the correct procedure to be followed, and the fact that continuation of the improper practice may result in administrative sanctions. The PSC or Medicare contractor BI unit shall document contacts and/or warnings with written reports and correspondence and place them in the investigation file. If the improper practices continue, the PSC or Medicare contractor BI unit shall consult with the OIG/OI contact person regarding sanction action.

If the provider continues aberrant billing practices during the period for which it is being investigated for possible sanction, the PSC or Medicare contractor BI unit shall initiate the adjustment of payments accordingly with the AC or appropriate unit in the Medicare contractor. After meeting with a provider, the PSC or Medicare contractor shall prepare a detailed report for the investigation file, and shall forward a copy to OIG/OI along with a case referral, if requested. The report shall include the information in A, B, and C below.

A. Background of Provider (Specialty)

PSCs and Medicare contractor BI units shall include a list of all enterprises in which the subject had affiliations, the states where the provider is licensed, all past complaints, and all prior educational contacts/notices.

B. Total Medicare Earnings

PSCs and Medicare contractor BI units shall include a report of the total Medicare earnings for the past 12 months, as well as total dollars for assigned and non-assigned claims in that period in the case file.

The report shall include the following:

- Earnings for the procedures or services in question
- Frequency of billing for these procedures/services
- Total number of claims submitted for these procedures/services

C. Extent of Audit Performed

The PSCs and Medicare contractor BI units shall include:

- A report of your audit process and findings
- Overpayment identified
- Recommendation(s)

D. Report of Meeting

The PSCs and Medicare contractor BI units include:

- Minutes from the meeting describing the problems and/or aberrancies discussed with the provider and the education provided to the provider to correct those problems, and
- Copies of educational materials given to the provider before, during, or subsequent to the meeting.

4.16 – AC and PSC Coordination on Voluntary Refunds

(Rev. 144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)

Voluntary refund checks payable to the Medicare program shall not be returned, regardless of the amount of the refund. The PSC or Medicare contractor BI unit shall communicate with the AC or Medicare contractor staff responsible for processing voluntary refunds to obtain information on voluntary refund checks received. The PSC or Medicare contractor BI unit shall perform an investigation on any voluntary refunds where there is suspicion of inappropriate payment or if a provider is under an active investigation.

Should the PSC or Medicare contractor BI unit receive a voluntary refund check in error, the PSC shall coordinate the transfer of voluntary refund checks to the AC through the JOA, and the Medicare contractor BI unit shall transfer the check to the appropriate Medicare contractor staff.

The ACs and the appropriate Medicare contractor staff *shall* refer to the Financial Management Manual for instructions on processing and reporting unsolicited/voluntary refunds received from providers/physicians/suppliers.

Through the JOA, PSCs shall establish a mechanism whereby the AC notifies the PSC on a regular basis of all voluntary refunds received by the AC. Medicare contractor BI units shall work with the appropriate area in the Medicare contractor to receive such notification. PSCs or ACs and Medicare contractor BI units shall send one letter annually (calendar year) to *any* provider *that* submits a voluntary refund *during that*

calendar year, advising the provider of the following:

The acceptance of a voluntary refund in no way affects or limits the rights of the Federal Government or any of its agencies or agents to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.

The PSCs and ACs shall work out in the JOA whether the PSC or the AC sends the above language. The ACs may send the language above on a voluntary refund acknowledgement letter or on a Remittance Advice if this capability exists.

The PSCs and Medicare contractor BI units shall refer to Chapter 4, §4.4.1G and H for law enforcement requests for voluntary refund information.

4.17 – Reserved for Future Use

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

4.18 – Referral of Cases to Other Entities for Action

(Rev. 71, 04-09-04)

4.18.1 - Referral of Cases to the Office of the Inspector General/Office of Investigations

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The PSCs and Medicare contractor BI units shall identify cases of suspected fraud and shall make referrals of all such cases to the OIG/OI, regardless of dollar thresholds or subject matter. Matters shall be referred when the PSC or Medicare contractor BI unit has documented allegations, including but not limited to: a provider, beneficiary, supplier, or other subject, a) engaged in a pattern of improper billing, b) submitted improper claims with suspected knowledge of their falsity, or c) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity. In cases where providers' employees submit complaints, such cases shall be forwarded to the OIG immediately.

When a case has been referred to OIG/OI, OIG/OI has 90 calendar days to accept the referral, refer the case to the DOJ (for example, the FBI, AUSAs, etc.), or to reject the case. If the PSC or Medicare contractor BI unit does not hear from OIG/OI within the first 90 calendar days following referral, and repeated attempts by the PSC or Medicare contractor BI unit to find out the status of the case are unsuccessful, the PSC or Medicare contractor BI unit shall contact the FBI (if the FBI does not have the case referral, the PSC and Medicare contractor BI unit shall refer the case to them) and/or refer the case to any other investigative agency with interest in the case. The PSC or Medicare contractor BI unit shall follow up on this second referral to the FBI and any other investigative agency within 45 calendar days. Refer to the FID section of the PIM for the requirements on entering and updating referrals in the FID. If OIG/OI or other law enforcement agencies will not give a definite answer, contact the Primary GTL, Associate GTL, and

SME (if a PSC) or RO (if a Medicare contractor BI unit) for assistance. If OIG/OI or other law enforcement agencies do not accept the case or are still unwilling to render a decision on the case, even after the intercession of the Primary GTL/Associate GTL/SME or RO, PSCs and Medicare contractor BI units shall proceed with action to ensure the integrity of the Medicare Trust Fund (e.g., PSCs and Medicare contractor BI units shall discuss it with the AUSA and/or the OIG prior to taking administrative action).

The OIG/OI will usually exercise one or more of the following options when deciding whether to accept a case:

- Conduct a criminal and/or civil investigation
- Refer the case back to the PSC or Medicare contractor BI unit for administrative action/recovery of overpayment with no further investigation
- Refer the case back to the PSC or Medicare contractor BI unit for administrative action/recoupment of overpayment after conducting an investigation or after consulting with the appropriate AUSA's office
- Refer the case back to the PSC or Medicare contractor BI unit for administrative action/recoupment of overpayment after the AUSA's office has declined prosecution
- Refer the case to another law enforcement agency for investigation

Where OIG/OI conducts an investigation, OIG/OI will usually initiate ongoing consultation and communication with the PSC or Medicare contractor BI unit to establish evidence (i.e., data summaries, statements, bulletins) that a statutory violation has occurred.

In addition to referral of such cases to the OIG, PSCs and Medicare contractor BI units shall also identify and take additional corrective action and prevent future improper payment (for example, by placing the provider's or supplier's claims on prepayment review). In every instance, whether or not the investigation is a potential case and law enforcement referral, the first priority is to minimize the potential loss to the Medicare Trust Fund and to protect Medicare beneficiaries from any potential adverse effect. Appropriate action varies from case to case. In one instance, it may be appropriate to suspend payment pending further development of the case. In another instance, suspending payment may alert the provider to detection of the fraudulent activity and undermine a covert operation already underway, or being planned, by federal law enforcement. PSCs and Medicare contractor BI units shall continue to monitor the need for administrative action prior to the elapsing of the 90 days and thereafter, and consult with OIG or other law enforcement agencies before taking such measures. The OIG may provide the PSC or Medicare contractor BI unit with information that shall be considered in determining what corrective action should be taken. If law enforcement is unwilling to render a decision on administrative action or advises the PSC or Medicare contractor BI

unit against taking administrative action, the PSC shall contact the Primary GTL, Associate GTL, and SME and the Medicare contractor shall contact the RO. The Primary GTL, Associate GTL, and SME for a PSC and the RO for a Medicare contractor will decide whether or not to take administrative action.

The PSC or Medicare contractor BI unit shall alert and coordinate with OIG/OI, FBI, the civil and criminal divisions in the U.S. Attorney's Office, and the RO, of contemplated suspensions, denials, and overpayment recoveries where there is reliable evidence of fraud and a referral pending with the OIG/OI or FBI, or a case pending in a U.S. Attorney's Office that may be known or unknown to the PSC or Medicare contractor BI unit.

If the case is the focus of a national investigation, PSCs and Medicare contractor BI units shall not take action without first consulting with the Primary GTL, Associate GTL, and SME (if a PSC) or the RO (if a Medicare contractor BI unit), and the agency that has the lead for the investigation.

4.18.1.1 - Referral of Potential Fraud Cases Involving Railroad Retirement Beneficiaries **(Rev. 71, 04-09-04)**

The DHHS OIG has jurisdiction over investigations involving Railroad Retirement Beneficiaries (RRB). OIG will refer them to the carrier for RRB claims.

The RRB personnel occasionally can more readily obtain necessary information from beneficiaries, e.g., working through the Social Security Administration (SSA) office when the Part B beneficiary is a railroad annuitant with no SSA monthly benefit involvement. When suspected violations come to the attention of the RRB in its processing of claims, it is expected to check for the possibility of similar violations in Medicare claims processed for RRB as well.

4.18.1.2 - Immediate Advisements to the OIG/OI **(Rev. 144, Issued: 03-31-06, Effective: 05-01-06, Implementation: 05-01-06)**

The PSC or Medicare contractor BI unit shall immediately advise *the OIG/OI through a telephone communication to the Special Agent in Charge (SAC) or Assistant Special Agent in Charge (ASAC) and maintain internal documentation on these advisements* when it receives allegations with one or more of the following characteristics:

- Indications of PSC, AC, or Medicare contractor employee fraud.
- Cases involving an informant that is an employee or former employee of the suspect physician or supplier.
- Involvement of providers who have prior convictions for defrauding Medicare or who are currently the subject of an OIG fraud investigation.

- Situations involving the subjects of current program investigations.
- Multiple carriers involved with any one provider (OIFO coordinates activities with all involved carriers).
- Cases with, or likely to get, widespread publicity or involving sensitive issues.
- Allegations of kickbacks or bribes.
- Allegations of a crime by a federal employee.
- Indications that organized crime may be involved.
- Indications of fraud by a third-party insurer that is primary to Medicare.

For OIG Hotline complaints with one or more of the above characteristics, the PSC or Medicare contractor BI unit shall promptly telephone the SAC or ASAC and describe the nature of the allegations. This communication ensures that the SAC or ASAC knows about the allegations from the OIG Hotline and gives the PSC or Medicare BI unit an opportunity to request further direction (if such direction has not already been given) from the SAC. In addition, the PSC or Medicare contractor BI unit shall document the telephone conversation through a written communication (e.g., an e-mail or letter) to the SAC or ASAC. This approach ensures that Immediate Advisements are timely and provides an audit trail for the PSC or Medicare contractor BI unit.

The PSCs and Medicare contractor BI units shall not expend resources attempting to investigate the allegation until so directed by CMS and/or the OIG. For example, if a PSC or Medicare contractor BI unit receives an allegation of kickbacks, the PSC or Medicare contractor BI unit shall immediately advise the OIG of the allegation, but shall not initiate an independent PSC or Medicare contractor BI unit query until requested to do so by the OIG and guidance on the parameters of the query are provided by the OIG. *If the query requested by the OIG becomes costly or requires major resources or is outside the scope of the normal law enforcement requests (e.g., requesting the PSCs or Medicare contractor BI units to conduct an interview for the development of a kickback case), the PSCs shall discuss this with the GTL, Associate GTL, and SME before fulfilling the OIG query request; and the Medicare contractor BI units shall discuss this with the RO.*

When an “immediate advisement” is required, all available documentation received with the allegation shall be forwarded *to the OIG*, unless otherwise directed by OIG. However, the initial forwarding of the applicable information does not equate to the PSC or Medicare contractor BI unit completing the full referral package as defined in the PIM (see PIM Exhibit 16.1), and does not equate to a case referral to law enforcement.

Refer to the FID section of the PIM for entering immediate advisements into the FID.

4.18.1.3 - Program Safeguard Contractor and Medicare Contractor BI Unit Actions When Cases Are Referred to and Accepted by OIG/OI (Rev. 71, 04-09-04)

Even though OIG/OI or another law enforcement agency has accepted a case, it is incumbent on the PSC or Medicare contractor BI unit to continue to monitor and document the suspect provider's activities. Additional complaints or other information received shall be immediately forwarded to the appropriate agency. Also, PSCs and Medicare contractor BI units may still initiate action to suspend payments, deny payments, or to recoup overpayments.

4.18.1.3.1 - Suspension (Rev. 83, Issued: 08-27-04, Effective: 09-27-04, Implementation: 09-27-04)

If payment has not been suspended before OIG/OI accepts a case, PSCs and Medicare contractor BI units shall discuss suspending payments with OIG/OI where there is reliable and substantive evidence that overpayments have been made and are likely to continue. Where OIG/OI disagrees with the suspension on the grounds that it will undermine their law enforcement action and there is disagreement, PSCs and Medicare contractor BI units shall discuss the matter with their designated SME or RO. The SME or RO will then decide, after consulting with OIG/OI, whether the PSC or Medicare contractor BI unit should proceed with the suspension. Suspension of payment should not be delayed in order to increase an overpayment amount in an effort to make the case more attractive to law enforcement.

Continuing to pay claims submitted by a suspect provider for this purpose is not an acceptable reason for not suspending payment.

The PSCs and Medicare contractor BI units shall refer to PIM, Chapter 3, §3.9ff for suspension of payment instructions.

A. Record of Suspended Payments Regarding Providers Involved in Litigation

The PSCs or Medicare contractor BI units shall provide OIG/OI with current information, as requested, regarding total payments due providers on monies that are being withheld because those cases are being referred for fraud prosecution. (The OIG/OI sends notification of which potential fraud cases have been referred for prosecution.) These monies represent potential assets, against which offset is made to settle overpayments or to satisfy penalties in any civil action brought by the government. The total amount of withheld payments is also pertinent to any determination by the DOJ whether civil fraud prosecution action is pursued or a negotiated settlement attempted.

4.18.1.3.2 - Denial of Payments for Cases Referred to and Accepted by OIG/OI (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Where it is clear that the provider has not furnished the item or services, denial is the appropriate action. (See PIM Exhibit 14.) Before recommending denying payments, PSCs consult with their Primary GTL, Associate GTL, and SME, and Medicare contractor BI units consult with their RO.

4.18.1.3.3 - Recoupment of Overpayments **(Rev. 71, 04-09-04)**

The PSCs and Medicare contractor BI units shall seek to initiate recoupment of overpayments whenever there is a determination that Medicare has erroneously paid. Once an overpayment has been determined, the statute and regulations require that the overpayment be recovered, especially if the overpayment is not related to the matter that was referred to law enforcement (see PIM, chapter 3, §3.8ff). Upon transition of BI work to a PSC, the AC shall perform recoupment of all overpayments including sending the demand letter.

4.18.1.4 - OIG/OI Case Summary and Referral **(Rev. 71, 04-09-04)**

The PSCs and Medicare contractor BI units should use the following format when preparing summaries for referral to OIG/OI including where additional civil, criminal, Civil Monetary Penalty Law (CMPL), or sanctions action appears appropriate. They shall forward two copies of the referral and fact sheet to the OIG, and shall retain a copy of the summary in the case file.

A Case Referral Fact Sheet Format can be found in PIM Exhibit 16.1.
A Case Summary Format can be found in PIM Exhibit 16.2.

4.18.1.5 - Actions to be Taken When a Fraud Case is Refused by OIG/OI **(Rev. 71, 04-09-04)**

4.18.1.5.1 - Continue to Monitor Provider and Document Case File **(Rev. 71, 04-09-04)**

The PSCs and Medicare contractor BI units shall not close a case simply because it is not accepted by OIG/OI. Since the subject is likely to continue to demonstrate a pattern of fraudulent activity, they shall continue to monitor the situation and to document the file, noting all instances of suspected fraudulent activity, complaints received, actions taken, etc. This will strengthen the case if it is necessary to take further administrative action or there is a wish to resubmit the case to OIG/OI at a later date. If PSCs and Medicare contractor BI units do resubmit the case to OIG/OI, they shall highlight the additional information collected and the increased amount of money involved.

4.18.1.5.2 - Take Administrative Action on Cases Referred to and Refused by OIG/OI

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The PSCs and Medicare contractor BI units take immediate action to implement appropriate administrative remedies, including the suspension or denial of payments, and the recovery of overpayments (see PIM, chapter 3, §3.8ff). Because the case has been rejected by law enforcement, PSCs shall consult with the Primary GTL, Associate GTL, and SME, and Medicare contractor BI units shall consult with their RO concerning the imposition of suspension. They pursue administrative and/or civil sanctions by OIG where law enforcement has declined a case.

A. Denial/Referral Action for Erroneous Payment(s), Cases Not Meeting the Referral Threshold

Many instances of erroneous payments cannot be attributed to fraudulent intent. There will also be cases where there is apparent fraud, but the case has been refused by law enforcement. Where there is a single claim, deny the claim and collect the overpayment. Where there are multiple instances, deny the claims, collect the overpayment, and warn the provider. PSCs and Medicare contractor BI units shall refer the provider, as appropriate, to provider relations, medical review, audit, etc.

4.18.1.5.3 - Refer to Other Law Enforcement Agencies

(Rev. 71, 04-09-04)

If the OIG/OI declines a case that the PSC or Medicare contractor BI unit believes has merit, the PSC or Medicare contractor BI unit may refer the case to other law enforcement agencies, such as the FBI, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), RRB/OIG, and/or the MFCU.

The PSCs and Medicare contractor BI units should recommend administrative and/or civil sanctions (including exclusions) to the OIG where law enforcement has declined the case.

4.18.2 - Referral to State Agencies or Other Organizations

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The PSCs and Medicare contractor BI units shall refer instances of apparent unethical or improper practices or unprofessional conduct to state licensing authorities, medical boards, the QIO, or professional societies for review and possible disciplinary action. If a case requires immediate attention, they shall refer it directly to the state licensing agency or medical society and send a copy of the referral to the QIO.

Some state agencies may have authority to terminate, sanction, or prosecute under state law. It may be appropriate to refer providers to the state licensing agency, to the MFCU, or to another administrative agency that is willing and able to sanction providers that

either bill improperly or mistreat their patients (see PIM, chapter 4, §4.18.1.5.3 and §4.19ff). This option is strongly recommended in instances where federal law enforcement is not interested in the case.

In each state there is a Medicare survey and certification agency. It is typically within the Department of Health. The survey agency has a contract with CMS to survey and certify institutional providers as meeting or not meeting applicable Medicare health and safety requirements, called Conditions of Participation. Providers not meeting these requirements are subject to a variety of adverse actions, ranging from bans on new admissions to termination of their provider agreements. These administrative sanctions are imposed by the RO, typically after an onsite survey by the survey agency.

Ordinarily, PSCs and Medicare contractor BI units do not refer isolated instances of questionable professional conduct to medical or other professional societies and state licensing boards. However, in flagrant cases, or where there is a pattern of questionable practices, a referral is warranted. The MR and BI units shall confer before such referrals, to avoid duplicate referrals. There is no need to compile sufficient weight of evidence so that a conclusive determination of misconduct is made prior to the referral. Rather, PSCs Medicare contractor BI units ascertain the probability of misconduct, gather available information, and leave any further investigation, review, and disciplinary action to the appropriate professional society or state board. Consultation and agreement between the MR and BI unit shall precede any referral to these agencies.

The PSC shall work closely with their Primary GTLs, Associate GTLs, and SMEs and Medicare contractor BI units shall work closely with their RO BI coordinator on these referrals. The BI coordinator shall involve the necessary staff in CMS.

Concurrently, PSCs or Medicare contractor BI units shall notify OIG/OI of any referral to medical or other professional societies and state licensing boards in cases involving unethical or unprofessional conduct. They shall include with the notification to OIG/OI copies of all materials referred to the society or board. PSCs or Medicare contractor BI units shall send OIG/OI a follow-up report on significant developments. They shall notify OIG/OI about possible abuse situations when it appears that a harmful medical practice or a sanctionable practice is occurring or has occurred.

Notice of suspension should also be given to the Medicaid SURs since a significant percent of Medicare beneficiaries are eligible for both Medicare and Medicaid and Medicaid is paying co-payments.

4.18.3 - Referral to Quality Improvement Organizations **(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)**

Communication with the QIO is essential to discuss the potential impact of efforts to prevent abuse as well as efforts to ensure quality and access. More specifically, CMS expects dialogue between PSCs and the QIO to:

- Ensure that an LMRP does not set up obstacles to appropriate care
- Articulate the program safeguard concerns or issues related to QIO activities
- Be aware of QIO initiatives (e.g., a QIO project to encourage Medicare beneficiaries to get eye exams), so they do not observe an increase in utilization and label it overutilization

The PSCs should continue exchanging additional information such as data analysis methods, data presentation methods, and successful ways to interact with providers to change behavior. This includes special projects that PSCs and the QIO have determined to be mutually beneficial.

It is essential that the PSC manager maintain an ongoing dialogue with his/her counterpart(s) at other PSCs, particularly in contiguous states. This ensures that a comprehensive investigation is initiated in a timely manner and prevents possible duplication of investigation efforts.

The PSCs should maintain an ongoing dialogue with the QIOs. Intermediaries may make referrals to the QIO for review of inpatient claims when outpatient claims reveal a problem provider. If the PSC refers a provider to the state licensing agency or medical society, i.e., those referrals that need immediate response from the state licensing agency, it should also send a copy of the referral to the QIO. Also, PSCs shall notify the QIO on utilization and quality issues for Part A providers and physicians that are suspected of fraud and of referrals to OIG/OI.

The PSC shall coordinate the review of Part A acute care inpatient hospital claims and long term care hospital PPS claims (i.e., long term acute care, not SNFs) for benefit integrity purposes with the QIO. The PSC shall follow the definition of acute care inpatient prospective payment system (PPS) hospital found in PIM Chapter 1, §1.1.2 (http://www.cms.gov/manuals/108_pim/pim83c01.pdf). If the PSC investigation indicates a need to review Part A acute care inpatient PPS hospital medical records or long term care hospital PPS claim medical records, the PSC shall request the medical records directly from the provider and have them sent directly to the PSC. Upon receipt of the records, the PSC shall perform a billing and document review of the medical record. The PSC shall also review the medical records for medical necessity, as well as, any indications of potential fraud and abuse. The PSC shall not initiate any payment determination, provider education, overpayment calculation, or overpayment request based on these medical records. QIOs will conduct or initiate these activities as appropriate.

Following PSC review of the Part A acute care inpatient PPS hospital claims or long term care hospital PPS claims and medical records, if the PSC determines that no potential fraud and abuse has been committed, or if the PSC determines that potential fraud and abuse is likely but law enforcement rejects the case, the PSC shall refer the provider and

medical records back to the QIO for further medical review, provider education, or the initiation of overpayment calculation, payment determination, and overpayment request.

If the PSC wants to follow up with the AC on such referrals concerning the overpayments, the PSC should include this in the JOA.

If after the PSC reviews the Part A acute care inpatient PPS hospital claims or long term care hospital PPS claims and medical records, the PSC determines that potential fraud and abuse is likely, the PSC shall coordinate the case with law enforcement (per Law Enforcement Memorandum of Understanding). If law enforcement accepts the case, law enforcement may then coordinate directly with the QIO for any further medical review.

The PSC shall not involve the QIO in reviews at other types of hospitals.

4.19 - Administrative Sanctions **(Rev. 71, 04-09-04)**

The term “sanctions” represents the full range of administrative remedies and actions available to deal with questionable, improper, or abusive practices of practitioners, providers, and suppliers under the Medicare and Medicaid programs or any state health care programs as defined under §1128(h) of the Act. There are two purposes for these sanctions. First, they are designed to be remedial, to ensure that questionable, improper, or abusive practices are dealt with appropriately. Practitioners, providers, and suppliers are encouraged to correct their behavior and operate in accordance with program policies and procedures. Second, the sanctions are designed to protect the programs by ensuring that improper payments are identified and recovered and that future improper payments are not made.

The primary focus of this section is sanctions authorized in §1128 and §1128A of the Act (exclusions and CMPs). Other, less severe administrative remedies may precede the more punitive sanctions affecting participation in the programs. The corrective actions PSCs, ACs, and Medicare contractors shall initially consider are:

- Provider education and warnings
- Revocation of assignment privileges
- Suspension of payments (refer to PIM, chapter 3, §3.9ff)
- Recovery of overpayments (refer to PIM, chapter 3, §3.8ff)
- Referral of situations to state licensing boards or medical/professional societies

4.19.1 - The Program Safeguard Contractor’s, AC’s, and Medicare Contractor’s Role **(Rev. 71, 04-09-04)**

The AC shall be responsible for:

- Ensuring that no payments are made to provider/suppliers for a salaried individual who is excluded from the program. OIG, as it becomes aware of such employment situations, notifies providers that payment for services furnished to Medicare patients by the individual is prohibited and that any costs (salary, fringe benefits, etc.) submitted to Medicare for services furnished by the individual will not be paid. A copy of this notice is sent to the PSC or Medicare contractor BI unit and to the appropriate CMS RO.

The PSC and the AC shall work out the following in their JOA, and the Medicare contractor BI unit shall work out the following with the appropriate Medicare contractor unit(s):

- Furnishing any available information to the OIG/OI with respect to providers/suppliers requesting reinstatement.
- Reporting all instances where an excluded provider/supplier submits claims for which payment may not be made after the effective date of the exclusion.

The PSC or Medicare contractor BI unit shall also be responsible for:

- Contacting OIG/OI when it determines that an administrative sanction against an abusive provider/supplier is appropriate.
- Providing OIG/OI with appropriate documentation in proposed administrative sanction cases.

4.19.2 - Authority to Exclude Practitioners, Providers, and Suppliers of Services **(Rev. 71, 04-09-04)**

Section 1128 of the Act provides the Secretary of DHHS the authority to exclude various health care providers, individuals, and businesses from receiving payment for services that would otherwise be payable under Medicare, Medicaid, and all federal health care programs. This authority has been delegated to the OIG.

When an exclusion is imposed, no payment is made to anyone for any items or services in any capacity (other than an emergency item or service provided by an individual who does not routinely provide emergency health care items or services) furnished, ordered, or prescribed by an excluded party under the Medicare, Medicaid, and all federal health care programs. In addition, no payment is made to any business or facility, e.g., a hospital, that submits claims for payment of items or services provided, ordered, prescribed, or referred by an excluded party.

The OIG also has the authority under §1128(b)(6) of the Act to exclude from coverage items and services furnished by practitioners, providers, or other suppliers of health care services who have engaged in certain forms of program abuse and quality of care issues. In order to prove such cases, the PSC or Medicare contractor BI unit shall document a long-standing pattern of care where educational contacts have failed to change the abusive pattern. Isolated instances and statistical samples are not actionable. Medical doctors must be willing to testify.

Authority under §1156 of the Act is delegated to OIG to exclude practitioners and other persons who have been determined by a QIO to have violated their obligations under §1156 of the Act. To exclude, the violation of obligation under §1156 of the Act must be a substantial violation in a substantial number of cases or a gross and flagrant violation in one or more instances. Payment is not made for items and services furnished by an excluded practitioner or other person. Section 1156 of the Act also contains the authority to impose a monetary penalty in lieu of exclusion. Section 1156 exclusion actions and monetary penalties are submitted by QIOs to the OIG/OI.

Payment is not made for items and services furnished by an excluded practitioner or other person.

4.19.2.1 - Basis for Exclusion Under §1128(b)(6) of the Social Security Act (Rev. 71, 04-09-04)

Exclusions under §1128(b)(6) of the Act are effected upon a determination that a provider has done one of the following:

- Submitted or caused to be submitted claims or requests for payment under Medicare or a state health care program containing charges (or costs) for items or services furnished substantially in excess of its usual charges (or costs).
- Furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under Medicare or under a state health care program) substantially in excess of the needs of such patients or of a quality that does not meet professionally recognized standards of health care.

For purposes of the exclusion procedures, “furnished” refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items or services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.

4.19.2.2 - Identification of Potential Exclusion Cases (Rev. 71, 04-09-04)

The PSC or Medicare contractor BI unit shall review and evaluate abuse cases to determine if they warrant exclusion action. Examples of abuse cases suitable for exclusion include, but are not limited to:

- Providers who have been the subject of an adverse QIO finding.
- Providers whose claims must be reviewed continually because of repeated instances of overutilization.
- Providers who have been the subject of previous cases that were not accepted for prosecution because of the low dollar value, or who were the subject of previous cases that were settled without exclusion.
- Providers who furnish or cause to be furnished items or services that are substantially in excess of the patient's needs or are of a quality that does not meet professionally recognized standards of health care (whether or not eligible for benefits under Medicare, Medicaid, title V or title XX).
- Providers who are the subject of prepayment review for an extended period of time (longer than 6 months) who have not corrected their pattern of practice after receiving educational/warning letters.
- Providers who have been convicted of a program related offense (§1128(a) of the Social Security Act).
- Providers who have been convicted of a non-program related offense (e.g., a conviction related to neglect or abuse of a patient, or related to a controlled substance) (§1128(a) of the Social Security Act).

Also, §1833(a)(1)(D) of the Act provides that payment for clinical diagnostic laboratory tests is made on the basis of the lower of the fee schedule or the amount of charges billed for such tests. Laboratories are subject to exclusion from the Medicare program under §1128(b)(6)(A) of the Act where the charges made to Medicare are substantially in excess of their customary charges to other clients. This is true regardless of the fact that the fee schedule exceeds such customary charges.

Generally, to be considered for exclusion due to abuse, the practices have to consist of a clear pattern that the provider/supplier refuses or fails to remedy in spite of efforts on the part of the PSC, AC, Medicare contractor, or QIO groups. An exclusion recommendation is implemented only where efforts to get the provider/supplier to change the pattern of practice are unsuccessful. The educational or persuasive efforts are not necessary or desirable when the issues involve life-threatening or harmful care or practice.

If a case involves the furnishing of items or services in excess of the needs of the individual or of a quality that does not meet professionally recognized standards of health care, PSCs and Medicare contractor BI units shall make every effort to obtain reports

confirming the medical determination of their medical review from one or more of the following:

- The QIO for the area served by the provider/supplier
- State or local licensing or certification authorities
- QIO committees
- State or local professional societies
- Other sources deemed appropriate

4.19.2.3 - Development of Potential Exclusion Cases (Rev. 71, 04-09-04)

A. Case Considerations

When PSCs and Medicare contractor BI units recommend cases to OIG/OI for exclusion, they shall consider:

- The nature and seriousness of the acts in question
- Actions taken to persuade the provider/supplier to abstain from further questionable acts
- The experience gained from monitoring payments to the provider/supplier after corrective action was taken
- The degree of deterrence that might be brought about by exclusion
- The effects of exclusion on the delivery of health care services to the community
- Any other factors deemed appropriate

In cases recommended to OIG/OI for exclusion where there has **not** been a conviction, see 42 U.S.C. 1320 a-7(b).

Documentation for excessive services and charges shall include the length of time that the problem existed and the dollars lost by the program. Documentation of excessive services or poor quality of care requires a medical opinion from a qualified physician who must be willing to testify. All cases involving excessive services or poor quality of care shall also contain documentation of prior unsuccessful efforts to correct the problem through the use of less serious administrative remedies.

B. Notification to Provider

If, as a result of development of potential fraud or abuse, a situation is identified that meets one or more of the criteria in PIM Chapter 4, §4.19.2.1, PSCs and Medicare contractor BI units shall consult the OIG/OI/OCIG (Office of Counsel to the Inspector General) contact person. The OIG prepares and sends a written notice to the provider containing the following information:

- Identification of the provider.
- The nature of the problem.
- The health care services involved.
- The basis or evidence for the determination that a violation has occurred. In cases concerning medical services, make every effort to include reports and opinions from a QIO or a QIO committee, or a state/local professional society.
- The sanction to be recommended.
- An invitation to discuss the problem with PSC, Medicare contractor BI unit, and OIG/OI staff, or to submit written information regarding the problem.
- A statement that a recommendation for consideration of sanctions will be made to the OIG/OI within 30 days, if the problems are not satisfactorily resolved.

If the provider/supplier accepts the invitation to discuss the issues, PSCs and Medicare contractor BI units shall make a report of the meeting for the record. This does not have to be a professionally transcribed report. Copies of the letter to the provider/supplier and the provider response, or the summary of the meeting, shall be in the file.

The PSCs and Medicare contractor BI units shall refer cases that demonstrate a strong fraud potential to OIG/OI for investigation.

They notify OIG/OI of any cases that reach the level where a provider/supplier is notified of a problem in accordance with this section, even if the provider is convinced that there was a legitimate reason for the problem or that the problem has been corrected. PSCs and Medicare contractor BI units do not refer these cases to OIG/OI unless requested to do so.

The PSCs and Medicare contractor BI units document and refer cases involving harmful care as rapidly as possible. They handle OIG/OI requests for additional information as priority items.

C. Additional Information

Additional information that may be of value in supporting a proposal to exclude includes any adverse impact on beneficiaries, the amount of damages incurred by the programs, and potential program savings.

D. Mitigating Circumstances

Any significant factors that do not support a recommendation for exclusion or that tend to reduce the seriousness of the problem may be found in 42 CFR Part 1001 and are also considered. One of the primary factors is the impact of the sanction action on the availability of health care services in the community. PSCs and Medicare contractor BI units shall bring mitigating circumstances to the attention of OIG/OI when forwarding their sanction recommendation.

4.19.2.4 - Contents of Sanction Recommendation (Rev. 71, 04-09-04)

The PSCs and Medicare contractor BI units shall include in the sanction recommendation (to the extent appropriate) the following information:

- Identification of the subject, including the subject's name, address, date of birth, social security number, and a brief description of the subject's special field of medicine. If the subject is an institution or corporation, include a brief description of the type of services it provides and the names of its officers and directors.
- A brief description of how the violation was discovered.
- A description of the subject's fraudulent or abusive practices and the type of health service(s) involved.
- A case-by-case written evaluation of the care provided, prepared by the PSC's, AC's, or Medicare contractor's MR staff, which includes the patient's medical records. This evaluation shall cite what care was provided and why such care was unnecessary and/or of poor quality. (The reviewer may want to consult with someone from their RO OCSQ.) Medicare reimbursement rules shall not be the basis for a determination that the care was not medically necessary. The reviewer shall identify the specific date, place, circumstance, and any other relevant information. If possible, the reviewer should review the medical records of the care provided to the patient before and after the care being questioned.

NOTE: A minimum of 10 examples shall be submitted in support of a sanction recommendation under §1128(b)(6)(B). In addition, none of the services being used to support the sanction recommendations shall be over 2 years old.

- Documentation supporting the case referral, e.g., records reviewed, copies of any letters or reports of contact showing efforts to educate the provider, profiles of the

provider who is being recommended for sanction, and relevant information provided by other program administrative entities.

- Copies of written correspondence and written summaries of the meetings held with the provider regarding the violation.
- Copies of all notices to the party.
- Information on the amount billed and paid to the provider for the 2 years prior to the referral.
- Data on program monies on an assigned/non-assigned basis for the last 2 years, if available.
- Any additional information that may be of value in supporting the proposal to exclude or that would support the action in the event of a hearing.

NOTE: All documents and medical records should be legible.

4.19.2.5 - Notice of Administrative Sanction Action (Rev. 71, 04-09-04)

When OIG receives the sanction recommendation, it is reviewed by medical and legal staff to determine whether the anticipated sanction action is supportable.

OIG then develops a proposal and sends it to the provider, advising it of the recommended sanction period, the basis for the determination that excessive or poor-quality care has been provided, and its appeal rights. The provider is also furnished with a copy of all the material used to make the determination. This is the material that was previously forwarded to OIG with the initial sanction recommendation.

The provider has 30 days from the date on the proposal letter to submit:

- Documentary evidence and written argument against the proposed action, or
- A written request to present evidence or argument orally to an OIG official

OIG may extend the 30-day period. All additional information is reviewed by OIG, as well as by medical and/or legal personnel when necessary. In the event the provider requests an in-person review, it is conducted by OIG in Washington, D.C.

When a final determination is made to exclude a provider, OIG sends a written notice to the provider at least 20 days prior to the effective date of the action (see 42 CFR §1001.2003 for exceptions to the 20 day notice). The notice includes:

- The basis for the exclusion.

- The duration of the exclusion and the factors considered in setting the duration.
- The earliest date on which OIG accepts a request for reinstatement, and the requirements and procedures for reinstatement.
- Appeal rights.
- A statement that, should claims continue to be submitted during the period of sanction for which payments may not be made, the provider/supplier may be criminally prosecuted, subject to a CMP action and/or denied reinstatement.

4.19.2.5.1 - Notification to Other Agencies (Rev. 71, 04-09-04)

Concurrent with the mailing of the notice to the provider, OIG sends a notice to the state agency administering or supervising the administration of each state health care program, the appropriate state licensing board, and CMS. CMS is responsible for ensuring proper effectuation of sanction actions.

OIG also notifies the appropriate licensing agency, the public, and all known employers of the sanctioned provider.

The effective date of exclusion is 20 days from the date of the notice to the provider (see 42 CFR §1001.2003 for exceptions to the 20 day notice).

4.19.2.6 - Denial of Payment to an Excluded Party (Rev. 71, 04-09-04)

The PSCs shall not recommend payments to the AC, Medicare contractor BI units shall not recommend payments to the appropriate unit within the Medicare contractor, and ACs and Medicare contractors shall not make payment on any excluded individual or entity for items or services furnished, ordered, or prescribed in any capacity on or after the effective date of exclusion, except in the following cases:

- For inpatient hospital services or post-hospital SNF care provided to an individual admitted to a hospital or SNF before the effective date of the exclusion, make payment, if appropriate, for up to 30 days after that date.
- For home health services provided under a plan established before the effective date of exclusion, make payment, if appropriate, for 30 days after the date on the notice.
- For emergency items and services furnished, ordered, or prescribed (other than an emergency item or service furnished, ordered, or prescribed in a hospital

emergency room) payment may be made to an excluded provider on or after the effective date of exclusion.

4.19.2.6.1 - Denial of Payment to Employer of Excluded Physician (Rev. 71, 04-09-04)

If an excluded physician is employed in a hospital setting and submits claims for which payment is prohibited, the AC or Medicare contractor Part B carrier surveillance process usually detects and investigates the situation.

However, in some instances an excluded physician may have a salary arrangement with a hospital or clinic, or work in group practice, and may not directly submit claims for payment. If this situation is detected, Part B ACs or Part B Medicare contractors:

- Contact the hospital/clinic/group practice and inform them that they are reducing the amount of their payment by the amount of federal money involved in paying the excluded physician
- Develop and refer to the PSC or Medicare contractor BI unit as a CMP case.

Upon referral from the AC or Medicare contractor, the PSC or Medicare contractor BI unit shall finalize the case and refer it to the OIG.

4.19.2.6.2 - Denial of Payment to Beneficiaries and Others (Rev. 71, 04-09-04)

If claims are submitted after the effective date of the exclusion by a beneficiary for items or services furnished, ordered, or prescribed by an excluded provider in any capacity, ACs or Medicare contractors shall:

- Pay the first claim submitted by the beneficiary and immediately give notice of the exclusion.
- Do not pay the beneficiary for items or services provided by an excluded party more than 15 days after the date of the notice to the beneficiary or after the effective date of the exclusion, whichever is later. The regulatory time frame is 15 days; however, CMS allows an additional 5 days for mailing.

If claims are submitted by a laboratory or DME company for any items or services ordered by a provider in any capacity excluded under §1156, or any items or services ordered or prescribed by a physician excluded under §1128, ACs or Medicare contractors shall handle the claims as above.

A. Notice to Beneficiaries

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, ACs or Medicare contractors shall include the following language in the notice: “We have received your claim for services furnished or ordered by _____ on _____. Effective _____, _____ was excluded from receiving payment for any items and services furnished in any capacity to Medicare beneficiaries. This notice is to advise you that no payment will be made for any items or services furnished by _____ if rendered more than 20 days from the date of this notice.”

B. Notice to Others

The Medicare Patient and Program Protection Act of 1987 provides that payment is denied for any items or services ordered or prescribed by a provider excluded under §§1128 or 1156. It also provides that payment cannot be denied until the supplier of the items and services has been notified of the exclusion.

If claims are submitted by a laboratory or a DME company for any items or services ordered or prescribed by a provider excluded under §§1128 or 1156, ACs and Medicare contractors shall:

- Pay the first claim submitted by the supplier and immediately give notice of the exclusion.
- Do not pay the supplier for items or services ordered or prescribed by an excluded provider in any capacity if such items or services were ordered or prescribed more than 20 days after the date of notice to the supplier, or after the effective date of the exclusion, whichever is later.

To ensure that the notice to the supplier indicates the proper reason for denial of payment, ACs and Medicare contractors shall include the following language in the notice:

“We have received your claim for services ordered or prescribed by _____ on _____. Effective _____, _____ was excluded from receiving payment for items or services ordered or prescribed in any capacity for Medicare beneficiaries. This notice is to advise you that no payment will be made for any items or services ordered or prescribed by _____ if ordered or prescribed more than 20 days from the date of this notice.”

4.19.3 - Appeals Process **(Rev. 71, 04-09-04)**

An excluded provider may try to have the decision reversed or modified, through the appeals process. The Departmental Appeals Board is responsible for processing hearing requests received from sanctioned providers except in very limited circumstances. Exclusions remain in effect during the appeals process (see 42 CFR §§1001.901 (false claims), 1001.951 (kickbacks), 1001.1601 (violations of the limitation on physician

charges), or 1001.1701 (billing for services of assistant-at-surgery during cataract operations)).

4.19.4 - Reinstatements **(Rev. 71, 04-09-04)**

A provider may apply for reinstatement when the basis for exclusion has been removed, at the expiration of the sanction period, or any time thereafter. PSCs and Medicare contractor BI units shall refer all requests they receive for reinstatement to the Office of Investigation of the OIG. Also, they furnish, as requested, information regarding the subject requesting reinstatement. OIG notifies the PSC and Medicare contractor BI unit in the state where the subject lives/practices of all reinstatements.

4.19.4.1 - Monthly Notification of Sanction Actions **(Rev. 71, 04-09-04)**

The Medicare Exclusion Database is a standard format, cumulative exclusion database that contains information on all exclusions and reinstatement actions in Medicare, Medicaid, and other federal health care programs. CMS receives this information from the Office of Inspector General monthly.

The PSCs, ACs, and Medicare contractors shall use the information contained in the MED and the GAO Debarment list to:

- Determine whether a physician/practitioner/provider or other health care supplier who seeks approval as a provider of services in the Medicare/Medicaid programs is eligible to receive payment
- Ensure that sanctioned providers are not being inappropriately paid

The dates reflected on the MED are the effective dates of the exclusion. Exclusion actions are effective 20 days from the date of the notice. Reinstatements or withdrawals are effective as of the date indicated.

The MED shows the names of a number of individuals and entities where the sanction period has expired. These names appear on the MED because the individual or entity has not been granted reinstatement. Therefore, the sanction remains in effect until such time as reinstatement is granted.

The PSCs, ACs, and Medicare contractors shall check their systems to determine whether any physician, practitioner, provider, or other health care worker or supplier is being paid for items or services provided subsequent to the date they were excluded from participation in the Medicare program. In the event a situation is identified where inappropriate payment is being made, they shall notify OIG and take appropriate action to correct the situation. Also, PSCs and Medicare contractor BI units shall consider the instructions contained in the CMP section of the PIM (PIM Chapter 4, §4.20ff).

The PSCs shall work with ACs to document a process in the JOA to make the AC aware of any payments to an excluded provider.

The ACs and Medicare contractors shall ensure that no payments are made after the effective date of a sanction, except as provided for in regulations at 42 CFR 1001.1901(c) and 489.55.

The ACs and Medicare contractors shall check payment systems periodically to determine whether any individual or entity who has been excluded since January 1982 is submitting claims for which payment is prohibited. If any such claims are submitted by any individual in any capacity or any entity who has been sanctioned under §§1128, 1862(d), 1156, 1160(b) or 1866(b) of the Act, PSCs and Medicare contractor BI units shall forward them to OIG/OI.

Also, ACs and Medicare contractors shall refer to the RO all cases that involve habitual assignment violators. In cases where there is an occasional violation of assignment by a provider, they shall notify the provider in writing that continued violation could result in a penalty under the CMPL.

4.20 - Civil Monetary Penalties

(Rev. 71, 04-09-04)

4.20.1 - Background

(Rev. 71, 04-09-04)

Background includes Basis of Authority, Purpose, Administrative Actions, and Documents.

4.20.1.1 - Basis of Authority

(Rev. 71, 04-09-04)

In 1981, Congress added §1128A (42 U.S.C. 1320a-7a) to the Social Security Act to authorize the Secretary of Health and Human Services to impose civil monetary penalties (CMPs). Since the enactment of the first CMP authority in 1981, Congress has increased both the number and types of circumstances under which CMPs may be imposed. Most of the specific statutory provisions authorizing CMPs also permit the Secretary to impose an assessment in addition to the CMP. An assessment is an additional monetary payment in lieu of damages sustained by the government because of the improper claim. Also, for many statutory violations, the Secretary may exclude the individual or entity violating the statute from participating in Medicare and other federal health care programs for specified periods of time.

In October 1994, the Secretary realigned the responsibility for enforcing these CMP authorities between the Centers for Medicare & Medicaid Services and the Office of the Inspector General. CMS was delegated the responsibility for implementing CMPs that involve program compliance. The OIG was delegated the responsibility for implementing

CMPs that involve threats to the integrity of the Medicare or Medicaid programs, i.e., those that involve fraud or false representations. On August 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) was enacted. This law provides for higher maximum CMPs (\$10,000 per false item or service on a claim or instance of non-compliance, instead of \$2,000 per item or service), and higher assessments (three times the amount claimed, instead of twice the amount) for some of the violations.

4.20.1.2 - Purpose **(Rev. 71, 04-09-04)**

The central purpose of the CMP process is to promote compliance with the program rules and regulations. To achieve this, CMS and its PSCs, ACs, and Medicare contractors shall enforce the regulatory standards and requirements.

The ACs and Medicare contractors shall educate the industry and the public regarding compliance. PSCs, ACs, and Medicare contractors shall have a statutory obligation to ensure compliance with regulations. Therefore, the efforts of ACs and Medicare contractors to achieve compliance shall be directed toward promoting a clear awareness and understanding of the program through education. When these efforts for achieving voluntary compliance have failed, formal enforcement action shall be referred to the appropriate agency.

4.20.1.3 - Enforcement **(Rev. 71, 04-09-04)**

An essential part of enforcement is that potential violations be discovered at the earliest possible time. Every alleged violation should be identified, developed, and processed in a timely manner. Delays in developing and/or processing the violations affect the program in several ways. First, such delays may permit an unsafe medical condition to prevail if prompt corrective action is not taken. Second, delays tend to improperly de-emphasize the seriousness of the violation. Lastly, delays diminish the deterrent effect.

4.20.1.4 - Administrative Actions **(Rev. 71, 04-09-04)**

PSCs, ACs, and Medicare contractors shall ensure that the program rules and regulations are being appropriately followed. If violations are noted (either through internal reviews or through a complaint process), ACs and Medicare contractors shall take the appropriate steps to inform and educate the provider of the non-compliance and encourage future compliance.

If, after a period of time, there is no significant change by the provider (the non-compliance continues), then a final warning notice of plans to propose a corrective action (such as a CMP) shall be issued by the AC or Medicare contractor. This notice shall be sent by certified mail (return receipt required) to ensure its receipt by the provider. The

notice shall indicate that previous notifications sent to the provider failed to correct the problem, and that this is a final warning. Additionally, it shall indicate that any further continuation of the non-compliance will result in the matter being forwarded to CMS or the OIG for administrative enforcement. While not specifically assessing a monetary penalty amount, the notice shall indicate that this is one type of sanction that may be applied.

4.20.1.5 - Documents **(Rev. 71, 04-09-04)**

Documentary evidence is extremely important in the CMP process. It is not only the evidence needed to support the administrative actions, but also a tool used for cross-referencing, verifying statements, and/or providing backup or background information.

Documentary evidence shall be identified, accounted for, and protected from loss, damage, or alteration. When copies of documents are made, care shall be taken to ensure that all copies are legible and accurate. Wherever possible, documents or copies shall be preserved in their original state; making marks on the face of the documents shall be avoided. If marks or explanations are necessary for explanation or clarification, include an additional copy of the document with marks on the copy.

4.20.2 - Civil Monetary Penalty Authorities **(Rev. 71, 04-09-04)**

The following sections list the authorities under which CMS's Program Integrity Group and the OIG may impose civil money penalties, assessments, and/or exclusions for program non-compliance.

4.20.2.1 - Civil Monetary Penalties Delegated to CMS **(Rev. 71, 04-09-04)**

The following is a brief description of authorities from the Social Security Act:

- Section 1806(b)(2)(B) - Any person or entity that fails to provide an itemized statement describing each item or service requested by a Medicare beneficiary.
- Section 1833(h)(5)(D) - Any person billing for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also cause an assessment and an exclusion.)
- Section 1833(i)(6) - Any person billing for an intraocular lens inserted during or after cataract surgery for which payment may be made for services in an ambulatory surgical center.

- Section 1833(q)(2)(B) - When seeking payment on an unassigned basis, any entity failing to provide information about a referring physician, including the referring physician's name and unique physician identification number. (This violation may also cause an exclusion.)
- Sections 1834(a)(11)(A) and 1842(j)(2) - Any supplier of durable medical equipment charging for covered items (furnished on a rental basis) after the rental payments may no longer be made (except for maintenance and servicing) as provided in §1834(a)(7)(A) of the Act. (This violation may also cause an assessment and an exclusion.)
- Section 1834(a)(17)(C) - Unsolicited telephone contacts by any supplier of durable medical equipment to Medicare beneficiaries regarding the furnishing of covered services. (This violation may only cause an exclusion.)
- Sections 1834(a)(18)(B) and 1842(j)(2) - Any durable medical equipment supplier that fails to make a refund to Medicare beneficiaries for a covered item for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also cause an assessment and an exclusion.)
- Sections 1834(b)(5)(C) and 1842(j)(2) - Any non-participating physician or supplier that charges a Medicare beneficiary more than the limiting charge as specified in §1834(b)(5)(B) of the Act for radiologist services. (This violation may also cause an assessment and an exclusion.)
- Sections 1834(c)(4)(C) and 1842(j)(2) - Any non-participating physician or supplier charging a Medicare beneficiary more than the limiting charge for mammography screening, as specified in §1834(c)(3) of the Act. (This violation may also cause an assessment and an exclusion.)
- Sections 1834(h)(3) and 1842(j)(2) - Any supplier of durable medical equipment, prosthetics, orthotics, and supplies charging for a covered prosthetic device, orthotic, or prosthetic (furnished on a rental basis) after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also cause an assessment and an exclusion.)
- Section 1834(h)(3) - Unsolicited telephone contacts by any supplier of durable medical equipment, prosthetics, orthotics to Medicare beneficiaries regarding the furnishing of prosthetic devices, orthotics, or prosthetics. (This violation may only cause an exclusion.)
- Section 1834(j)(2)(A)(iii) - Any durable equipment supplier that completes the medical necessity section on the certificate of medical necessity or fails to provide the fee schedule amount and the supplier's charge for the medical equipment or supply prior to distributing the certificate to the physician.

- Sections 1834(j)(4) and 1842(j)(2) - Any supplier of durable medical equipment, prosthetics, orthotics, and supplies that fails to make refunds in a timely manner to Medicare beneficiaries (for items or services billed on a non-assigned basis) if the supplier does not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined not to be medically necessary or reasonable. (This violation may also cause an assessment and an exclusion.)
- Sections 1834(k)(6) and 1842(j)(2) - Any practitioner or other person that bills or collects for outpatient therapy services or comprehensive outpatient rehabilitation services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)
- Section 1842(b)(18)(B) - For practitioners specified in §1842(b)(18)(C) of the Act (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists), any practitioner billing (or collecting) for any services on a non-assigned basis. (This violation may also cause an assessment and an exclusion.)
- Section 1842(k) - Any physician presenting a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987. (This violation may also cause an assessment and an exclusion.)
- Section 1842(l)(3) - Any non-participating physician who does not accept payment on an assigned basis and who fails to refund beneficiaries for services that are not reasonable or medically necessary or are of poor quality. (This violation may also cause an assessment and an exclusion.)
- Section 1842(m)(3) - Any non-participating physician billing for an elective surgical procedure on a non-assigned basis, who charges at least \$500, fails to disclose charge and coinsurance amounts to the Medicare beneficiary prior to rendering the service, and fails to refund any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (This violation may cause an assessment and an exclusion.)
- Section 1842(n)(3) - Any physician billing diagnostic tests in excess of the scheduled fee amount. (This violation may cause an assessment and an exclusion.)
- Section 1842(p)(3)(A) - Any physician that fails to promptly provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill submitted on a non-assigned basis.
- Section 1842(p)(3)(B) - Any physician failing to provide the diagnosis code or codes after repeatedly being notified by CMS of the obligations on any request for

payment or bill submitted on a non-assigned basis. (This violation is only subject to an exclusion.)

- Section 1848(g)(1)(B) - Any non-participating physician, supplier, or other person who furnishes physicians' services and bills on a non-assigned basis, or collects in excess of the limiting charge, or fails to make an adjustment or refund to the Medicare beneficiary. (This violation may cause an assessment and an exclusion.)
- Section 1848(g)(3) - Any person billing for physicians' services on a non-assigned basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may cause an assessment and an exclusion.)
- Section 1848(g)(4) - Any physician, supplier, or other person (except one excluded from the Medicare program) that fails to submit a claim for a beneficiary within one year of providing the service; or imposes a charge for completing and submitting the standard claims form. (This violation may cause an exclusion.)
- Section 1862(b)(5)(C) - Any employer who (before October 1, 1998) fails to provide an employee's group health insurance coverage information to the Medicare contractor.
- Section 1862(b)(6)(B) - Any entity that fails to complete a claim form relating to the availability of other health benefit plans, or provides inaccurate information relating to the availability of other health plans on the claim form.
- Section 1877(g)(5) - Any person failing to report information concerning ownership, investment, and compensation arrangements. (This violation may cause an assessment and an exclusion.)
- Section 1879(h) - Any durable medical equipment supplier (including a supplier of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies) failing to make refunds to Medicare beneficiaries for items or services billed on an assigned basis if the supplier did not possess a Medicare supplier number, if the item or service is denied in advance, or if the item or service is determined to be not medically necessary or reasonable. (This violation may cause an assessment and an exclusion.)
- Section 1882(a)(2) - Any person who issues a Medicare supplemental policy that has not been approved by the state regulatory program or does not meet federal standards. (This violation may cause an assessment and an exclusion.)
- Section 1882(p)(8) - Any person who sells or issues non-standard Medicare supplemental policies. (This violation may cause an assessment and an exclusion.)

- Section 1882(p)(9)(C) - Any person who sells a Medicare supplemental policy and fails to make available the core group of basic benefits as part of its product line; or fails to provide the individual (before the sale of the policy) an outline of coverage describing the benefits provided by the policy. (This violation may cause an assessment and an exclusion.)
- Section 1882(q)(5)(C) - Any person who fails to suspend a Medicare supplemental policy at the policyholder's request (if the policyholder applies for and is determined eligible for Medicaid); or to automatically reinstate the policy as of the date the policyholder loses medical assistance eligibility (and the policyholder provides timely notice of losing his or her Medicaid eligibility). (This violation may cause an assessment and an exclusion.)
- Section 1882(r)(6)(A) - Any person that fails to refund or credit as required by the supplemental insurance policy loss ratio requirements. (This violation may cause an assessment and an exclusion.)
- Section 1882(s)(4) - Any issuer of a Medicare supplemental policy that does not waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare policy; or denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria. (This violation may cause an assessment and an exclusion.)
- Section 1882(t)(2) - Any issuer of a Medicare supplemental policy who fails to provide medically necessary services to enrollees through the issuer's network of entities; imposes premiums on enrollees in excess of the premiums approved by the state; acts to expel an enrollee for reasons other than non-payment of premiums; does not provide each enrollee at the time of enrollment with specific information regarding policy restrictions; or fails to obtain a written acknowledgment from the enrollee of receipt of the information. (This violation may cause an assessment and an exclusion.)

4.20.2.2 - Civil Monetary Penalties Delegated to OIG

(Rev. 101, Issued: 01-28-05, Effective: 02-28-05, Implementation: 02-28-05)

The following is a brief description of authorities from the Social Security Act:

Section 1128(a)(1)(A), (B)	False or fraudulent claim for item or service including incorrect coding (upcoding) or medically unnecessary services.
Section 1128A(a)(1)(C)	Falsely certified specialty.

Section 1128A(a)(1)(D)	Claims presented by excluded party.
Section 1128A(a)(1)(E)	Pattern of claims for unnecessary services or supplies.
Section 1128A(a)(2)	Assignment agreement, Prospective Payment System (PPS) abuse violations.
Section 1128A(a)(3)	PPS false/misleading information influencing discharge decision.
Section 1128A(a)(4)	Excluded party retaining ownership or controlling interest in participating entity.
Section 1128A(a)(5)	Remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.
Section 1128A(a)(6)	Contracting with an excluded individual.
Section 1128A(a)(7)	Improper remuneration; i.e., kickbacks.
Section 1128A(b)	Hospital physician incentive plans.
Section 1128A(b)(3)	Physician falsely certifying medical necessity for home health benefits.
Section 1128E(b)	Failure to supply information on adverse action to the Health Integrity and Protection Data Bank (HIPDB).
Section 1140(b)(1)	Misuse of Departmental symbols/emoles.
Section 1819(b)(3)(B) Section 1919(b)(3)(B)	False statement in assessment of functional capacity of skilled nursing facility (SNF) resident.
Section 1819(g)(2)(A) Section 1919 (g)(2)(A)	Notice to SNF/nursing facility of standard scheduled survey.
Section 1857(g)(1)(F)	Managed care organization (MCO) fails to comply with requirements of §1852(j)(3) or §1852(k)(2)(A)(ii). (Prohibits MCO interference with the provider's advice to an enrollee; mandates that providers not affiliated with the MCO may not bill or collect in excess of the limiting charge.)
Section 1860D-31(i)(3)	Engaged in false or misleading marketing practices under the Medicare prescription drug discount card program; or overcharge prescription drug enrollees; or misuse of transitional assistance funds.
Section 1862(b)(3)(c)	Financial incentives not to enroll in a group health

	plan.
Section 1866(g)	Unbundling outpatient hospital costs.
Section 1867	Dumping by hospital/responsible physician of patients needing emergency medical care.
Section 1876(i)(6)(A)(i) Section 1903(m)(5)(A)(i) Section 1857(g)(1)(A)	Failure by Health Maintenance Organization (HMO)/competitive medical plan/MCO to provide necessary care affecting beneficiaries.
Section 1876(i)(6)(A)(ii) Section 1903(m)(5)(A)(ii) Section 1857(g)(1)(B)	Premiums by HMO/competitive medical plan/MCO in excess of permitted amounts.
Section 1876(i)(6)(A)(iii) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(C)	HMO/competitive medical plan/MCO expulsion/refusal to re-enroll individual per prescribed conditions.
Section 1876(i)(6)(A)(iv) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(D)	HMO/competitive medical plan/MCO practices to discourage enrollment of individuals.
Section 1876(i)(6)(A)(v) Section 1903(m)(5)(A)(iii) Section 1857(g)(1)(E)	False or misrepresenting HMO/competitive medical plan/MCO information to Secretary.
Section 1876(i)(6)(A)(vi) Section 1903(m)(5)(A)(v) Section 1857(f)	Failure by HMO/competitive medical plan/MCO to assure prompt payment for Medicare risk-sharing contracts only or incentive plan provisions.
Section 1876(i)(6)(A)(vii) Section 1857(g)(1)(G)	HMO/competitive medical plan/MCO hiring/employing person excluded under §1128 or §1128A.
Section 1877(g)(3)	Ownership restrictions for billing clinical lab services.
Section 1877(g)(4)	Circumventing ownership restriction governing clinical labs and referring physicians.
Section 1882(d)(1)	Material misrepresentation referencing compliance of Medicare supplemental policies (including Medicare + Choice).
Section 1882(d)(2)	Selling Medicare supplemental policy (including Medicare + Choice) under false pretense.
Section 1882(d)(3)(A)	Selling health insurance that duplicates benefits.

Section 1882(d)(3)(B)	Selling or issuing Medicare supplemental policy (including Medicare + Choice) to a beneficiary without obtaining a written statement from beneficiary with regard to Medicaid status.
Section 1882(d)(4)(A)	Use of mailings in the sale of non-approved Medicare supplemental insurance (including Medicare + Choice).
Section 1891(c)(1)	Notifying home health agency of scheduled survey.
Section 1927(b)(3)(B)	False information on drug manufacturer survey from manufacturer/wholesaler/seller.
Section 1927(b)(3)(C)	Provision of untimely or false information by drug manufacturer with rebate agreement.
Section 1929(i)(3)	Notifying home- and community-based care providers/settings of survey.
Section 421(c) of the Health Care Quality Improvement Act (HCQIA)	Failure to report medical malpractice liability to National Practitioner Data Bank.
Section 427(b) of HCQIA	Breaching confidentiality of information report to National Practitioner Data Bank.

4.20.3 - Referral Process (Rev. 71, 04-09-04)

4.20.3.1 - Referral Process to CMS (Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Compliance is promoted through both administrative and formal legal actions. Administrative compliance action shall first be attempted by ACs and Medicare contractors through education and warning letters that request the provider to comply with Medicare's rules and regulations. If the provider fails to take corrective action and continues to remain non-compliant, the AC shall make a referral to the PSC who shall forward it to the Primary GTL, Associate GTL, and SME and the CMS CO Director of the Division of Benefit Integrity Management Operations (see PIM Chapter 4, §4.20.3.2). The Medicare contractor shall make a referral to the Medicare contractor BI unit who shall prepare a referral of a CMP case and shall forward it to its respective CMS RO component that has oversight of the Medicare Integrity Program and CMS CO DBIMO (see PIM Chapter 4, §4.20.3.2).

It is important for ACs and Medicare contractors to promote program compliance in their respective jurisdictions. The ACs and Medicare contractors shall ensure that all materials presented to providers through education, published bulletins, or written communication are clear and concise and accurately represent the facts of compliance versus non-compliance. Providers shall also be allowed the opportunity to present additional facts that may represent mitigating circumstances. PSCs and Medicare contractor BI units shall consider this information in an objective manner before proceeding with a CMP referral to CMS.

When a PSC or Medicare contractor BI unit elects to make a CMP referral to CMS, the initial referral package shall consist of a brief overview of the case; supportive documentation is not required at such time. The initial referral package shall consist of:

1. Identification of the provider, including the provider's name, address, date of birth, Social Security number, Medicare identification number(s), and medical specialty. If the provider is an entity, include the names of its applicable owners, officers, and directors.
2. Identification of the CMP authorities to be considered (use the authorities identified in PIM Chapter 4, §4.20.2.1).
3. Identification of any applicable Medicare manual provisions.
4. A brief description of how the violations identified above were discovered, and the volume of violations identified.
5. Total overpayments due the program or the beneficiary(ies), respectively.
6. A brief chronological listing of events depicting communication (oral and written) between the AC or Medicare contractor and the provider.
7. A brief chronological listing of bulletins addressing the non-compliant area (starting with the bulletin released immediately prior to the first incident of non-compliance by the provider).
8. Any additional information that may be of value to support the referral.
9. The name and phone number of contacts at the PSC or Medicare contractor BI unit.

Upon receipt of the above information, CMS staff will review the materials and conduct follow-up discussions with the PSC or Medicare contractor BI unit regarding the referral. Within 90 days of receipt of the referral, CMS will notify the PSC or Medicare contractor BI unit of its decision to accept or decline the referral.

If CMS declines the referral, the PSC or Medicare contractor shall communicate this to the AC or the appropriate Medicare contractor unit to continue in their efforts to educate and promote compliance by the provider. The PSC or Medicare contractor BI unit shall also consider other (less severe) administrative remedies, which, at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to state licensing boards or medical/professional societies, where applicable. In all situations where inappropriate Medicare payments have been identified, ACs and Medicare contractors shall initiate the appropriate steps for recovery.

If CMS accepts the referral, the PSC and Medicare contractor BI unit shall provide any supportive documentation that may be requested, and be able to clarify any issues regarding the data in the case file or PSC, AC, and Medicare contractor processes.

4.20.3.2 - Referrals to OIG

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Upon discovery of any case that may implicate any of the OIG's delegated CMP authority, regardless of whether there is any other pending activity, or whether the fraud case was closed, the PSC or Medicare contractor BI unit shall contact the OIG/OI Field Office to discuss the potential case. If this contact results in a referral, the PSC or Medicare contractor BI unit shall follow the same referral format as described in PIM, chapter 4, §4.18.1.4. If a referral is not made or a referral is declined, the PSC or Medicare contractor BI unit shall consider other administrative remedies, which, at a minimum, may include revocation of assignment privileges, establishing prepayment or postpayment medical reviews, and referral of situations to state licensing boards or medical/professional societies, where applicable. In all situations where appropriate Medicare payments have been identified, ACs and Medicare contractors shall initiate the appropriate steps for recovery.

The PSC and Medicare contractor BI unit shall send to the OIG all cases, as appropriate, where an excluded provider or individual has billed or caused to be billed to the Medicare or Medicaid program for the furnishing of items or services after exclusion. Such misconduct is sanctionable under §1128A(a)(C)(1) of the Social Security Act.

The PSC or Medicare contractor BI unit shall send to CMS DBIMO all cases where the PSC or the Medicare contractor BI unit believes that misuse has occurred of the Medicare name, symbols, emblems, or other violations as described in §1140 of the Social Security Act and in 42 CFR 1003.102(b)(7). CMS will be responsible for referring these types of cases to OIG. All such cases shall be sent to the following CMS address:

Centers for Medicare & Medicaid Services
Division of Benefit Integrity Management Operations
Mail Stop C3-02-16
7500 Security Blvd
Baltimore, MD 21244

4.20.4 - CMS Generic Civil Monetary Penalties Case Contents (Rev. 71, 04-09-04)

The following information, if available, shall be included as part of the CMP case package and made available upon request by CMS:

1. Background information:
 - a. All known identification numbers (PIN, UPIN, etc.).
 - b. Provider's first and last name or entity name (if subject is an entity, also include the full name of the principal operator).
 - c. Provider's address (street, city, state, and zip code). If violator is an entity, identify address where principal operator personally receives his/her mail.
2. Copies of any interviews, reports, or statements obtained regarding the violation.
3. Copies of documentation supporting a confirmation of the violation.
4. Copies of all applicable correspondence between beneficiary and provider.
5. Copies of all applicable correspondence (including telephone contacts) between the AC or Medicare contractor and provider.
6. Copies of provider's applicable bills to beneficiaries and/or ACs and Medicare contractors, and associated payment histories.
7. Copies of any complaints regarding provider and disposition of the complaint.
8. Copies of all publications (e.g., bulletins, newsletters) sent to provider by the PSC, AC, or Medicare contractor who discuss the type of violation being addressed in the CMP case.
9. Copies of any monitoring reports regarding the provider.
10. Name and telephone number of PSC or Medicare contractor BI unit contact.

4.20.5 - Additional Guidance for Specific Civil Monetary Penalties (Rev. 71, 04-09-04)

4.20.5.1 - Beneficiary Right to Itemized Statement (Rev. 71, 04-09-04)

The following is background information for developing specific CMS CMP cases: Effective for services or items provided on or after January 1, 1999, §4311 of the Balanced Budget Act (BBA) provides that Medicare beneficiaries have the right to request and receive an itemized statement from their health care provider of service (e.g., hospital, nursing facility, home health agency, physician, non-physician practitioner, DMEPOS supplier). Upon receipt of this request, providers have 30 days to furnish the itemized statement to the beneficiary. Health care providers who fail to provide an itemized statement may be subject to a CMP of not more than \$100 for each failure to furnish the information (§1806(b)(2)(B) of the Social Security Act). An itemized statement is defined as a listing of each service(s) or item(s) provided to the beneficiary. Statements that reflect a grouping of services or items (such as a revenue code) are not considered an itemized statement.

A beneficiary who files a complaint with an AC or Medicare contractor regarding a provider's failure to provide an itemized statement must initially validate that his/her request was in writing (if available), and that the statutory 30-day time limit (calendar days) for receiving the information has expired. In most cases, an additional 5 calendar days should be allowed for the provider to receive the beneficiary's written request. If the beneficiary did not make his/her request in writing, inform him/her that he/she must first initiate the request to the provider in writing. It is only after this condition and the time limit condition are met that the AC or Medicare contractor may contact the provider.

Once the AC or Medicare contractor confirms that the complaint is valid, the AC or Medicare contractor shall initiate steps to assist the beneficiary in getting the provider to furnish the itemized statement. ACs and Medicare contractors shall initiate the same or similar procedures when receiving complaints regarding mandatory submission of claims (i.e., communicating with the provider about their non-compliance and the possibility of the imposition of a CMP).

If the intervention of the AC or Medicare contractor results in the provider furnishing an itemized statement to the beneficiary, the conditions for the statute are considered met, and a CMP case should not be developed. Should the intervention of the AC or Medicare contractor prove unsuccessful, the AC or Medicare contractor shall consider referral to the PSC or Medicare contractor BI unit for subsequent referral of the potential CMP case to CMS, following the guidelines established in PIM Chapter 4, §§4.20.3.1 and 4.20.4. There may be instances where a beneficiary receives an itemized statement and the AC or Medicare contractor receives the beneficiary's request (written or oral) to review discrepancies on his/her itemized statement. ACs and Medicare contractors shall follow their normal operating procedures in handling these complaints. ACs and Medicare contractors shall determine whether itemized services or items were provided, or if any other irregularity (including duplicate billing) resulted in improper Medicare payments. If so, the AC or Medicare contractor shall recover the improper payments.

4.20.5.2 - Medicare Limiting Charge Violations **(Rev. 71, 04-09-04)**

The Omnibus Budget Reconciliation Act of 1989 (OBRA) established a limitation on actual charges (balanced billing) by non-participating physicians. (Refer to §1848(g) of the Act, and Medicare Carriers Manual §§5000ff. and 7555, respectively, for further information.)

As a result of the reduction in limiting charge monitoring activities (i.e., the discontinuance of the Limiting Charge Exception Report and the Limiting Charge Monitoring Report, the discontinuance of sending compliance monitoring letters and Refund/Adjustment Verification Forms), developing a Limiting Charge CMP case shall require the following additional information:

- **Contact with the provider** - Based on CMS instructions, ACs and Medicare contractors are to assist beneficiaries in obtaining overcharge refunds from the providers. This assistance reinstates the activity of sending the refund verification forms and compliance monitoring letters respective to the beneficiary(ies) who request assistance. Copies of these communications will become part of the CMP case file. Ensure that the communication includes language that reminds the provider that the limiting charge amounts for most physician fee schedule services are listed on the disclosure reports they receive in their yearly participation enrollment packages. (This constitutes “notice” of the Medicare charge limits for those services.) The provider’s letter should also include information that describes “what constitutes a violation of the charge limit,” and that providers are provided notification on their copy of the remittance statements when they exceed the limiting charge. Providers who elected not to receive remittance statements for non-assigned claims should be reminded that they are still bound by the limiting charge rules, and that they are required to make refunds of overcharges. It may be appropriate at this time for providers to reconsider their decision not to receive remittance forms for non-assigned claims. Providers should also be informed of what action to take in order to receive these statements.
- **Limiting Charge Monitoring Reports (LCMRs)** - Produce LCMRs for all limiting charge violations respective to the provider and which encompasses the last three years. ACs and Medicare contractors shall also identify those beneficiaries appearing on the reports who have requested assistance in obtaining a refund from their provider.

4.21 - Monitor Compliance **(Rev. 71, 04-09-04)**

The PSCs and Medicare contractor BI units shall follow-up on all incidences of documented false claims to ensure that the problem has not recurred and no longer exists. They shall send a letter to the provider indicating that they are monitoring their actions.

4.21.1 - Resumption of Payment to a Provider - Continued Surveillance After Detection of Fraud **(Rev. 71, 04-09-04)**

After completion of the investigation and appropriate legal action, all determined overpayments are recouped by either direct refund or offset against payments being held in suspense. Once recoupment is completed, PSCs and Medicare contractor BI units shall release any suspended monies that are not needed to recoup determined overpayments and, if applicable, penalties.

PSCs and Medicare contractor BI units shall monitor future claims and related actions of the provider for at least 6 months, to assure the propriety of future payments. In addition to internal screening of the claims, if previous experience or future billings warrant, they shall periodically interview a sampling of the provider's patients to verify that billed services were actually furnished.

If, at the end of a 6-month period, there is no indication of a continuing aberrant pattern, PSCs and Medicare contractor BI units shall discontinue the monitoring.

4.22 - Discounts, Rebates, and Other Reductions in Price **(Rev. 71, 04-09-04)**

A PSC or Medicare contractor that learns of a questionable discount program shall contact OIG/OI to determine how to proceed. OIG/OI may ask for immediate referral of the matter for investigation.

4.22.1 - Anti-Kickback Statute Implications **(Rev. 71, 04-09-04)**

The Medicare and Medicaid anti-kickback statute provides as follows:

Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, hospital incentive or bribe) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or a State health care program, or in return for purchasing, leasing, or ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Medicare, Medicaid or a State health program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both. 42 U.S.C. 1320a-7b(b), §1128B(b) of the Act.

Discounts, rebates, or other reductions in price may violate the anti-kickback statute because such arrangements induce the purchase of items or services payable by Medicare or Medicaid. However, some arrangements are clearly permissible if they fall within a safe harbor. One safe harbor protects certain discounting practices. For purposes of this safe harbor, a "discount" is the reduction in the amount a seller charges a buyer for a good or service based on an arms-length transaction. In addition, to be protected under the discount safe harbor, the discount must apply to the original item or service which is

purchased or furnished, i.e., a discount cannot be applied to the purchase of a different good or service than the one on which the discount was earned. A “rebate” is defined as a discount that is not given at the time of sale. A buyer is the individual or entity responsible for submitting a claim for the item or service which is payable by the Medicare or Medicaid programs. A seller is the individual or entity that offers the discount.

4.22.1.1 - Marketing to Medicare Beneficiaries (Rev. 71, 04-09-04)

This section explains marketing practices that could be in violation of the Medicare anti-kickback statute, 42 U.S.C. 1320a-7b(b). These practices shall comply with the Medicare anti-kickback statute and with the Office of the Inspector General's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.

Marketing practices may influence Medicare beneficiaries who utilize medical supplies, such as blood glucose strips, on a repeated basis. Beneficiaries are advised to report any instances of fraudulent or abusive practices, such as misleading advertising and excessive or non-requested deliveries of test strips, to their Durable Medical Equipment Regional Carriers.

Advertising incentives that indicate or imply a routine waiver of coinsurance or deductibles could be in violation of 42 U.S.C. 1320a-7b(b). Routine waivers of coinsurance or deductibles are unlawful because they could result in 1) false claims, 2) violation of the anti-kickback statute, and/or 3) excessive utilization of items and services paid for by Medicare.

In addition, 42 U.S.C. 1320a-7a(a) (5) prohibits a person from offering or transferring remuneration. Remuneration is a waiver of coinsurance and deductible amounts, with exceptions for certain financial hardship waivers that are not prohibited.

Suppliers should seek legal counsel if they have any questions or concerns regarding waivers of deductibles and/or coinsurance or the propriety of marketing or advertising material.

Any supplier who routinely waives co-payments or deductibles can be criminally prosecuted and excluded from participating in federal health care programs.

4.22.2 - Cost-Based Payment (Intermediary Processing of Part A Claims): Necessary Factors for Protected Discounts (Rev. 71, 04-09-04)

For a discount to be protected, certain factors must exist. These factors assure that the benefit of the discount or rebate will be reported and passed on to the programs. If the buyer is a Part A provider, it must fully and accurately report the discount in its cost

report. The buyer may note the submitted charge for the item or service on the cost report as a “net discount.” In addition, the discount must be based on purchases of goods or services bought within the same fiscal year. However, the buyer may claim the benefit of a discount in the fiscal year in which the discount is earned or in the following year. The buyer is obligated, upon request by DHHS or a state agency, to provide information given by the seller relating to the discount.

The following types of discounts may be protected if they comply with all the applicable standards in the discount safe harbor:

- Rebate check
- Credit or coupon directly redeemable from the seller
- Volume discount or rebate

The following types of discounts are not protected:

- Cash payment
- Furnishing one good or service free of charge or at a reduced charge in exchange for any agreement to buy a different good or service
- Reduction in price applicable to one payer but not to Medicare or a state health care program
- Routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary

NOTE: There is a separate safe harbor for routine waiver of co-payments for inpatient hospital services.

4.22.3 - Charge-Based Payment (Intermediary Processing of Part B Claims): Necessary Factors for Protected Discounts (Rev. 71, 04-09-04)

For a discount program to be protected for Part B billing, certain factors shall exist. These factors assure that the benefit of the discount or other reduction in price is reported and passed on to the Medicare or Medicaid programs. A rebate rendered after the time of sale is not protected under any circumstances. The discount must be made at the time of sale of the good or service. In other words, rebates are not permitted for items or services if payable on the basis of charges. The discount must be offered for the same item or service that is being purchased or furnished. The discount must be clearly and accurately reported on the claim form.

Credit or coupon discounts directly redeemable from the seller may be protected if they comply with all the applicable standards in the discount safe harbor.

The following types of discounts are not protected:

- Rebates offered to beneficiaries
- Cash payment
- Furnishing an item or service free of charge or at a reduced charge in exchange for any agreement to buy a different item or service
- Reduction in price applicable to one payer but not to Medicare or a state health care program
- Routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary

NOTE: There is a separate safe harbor for routine waiver of co-payments for inpatient hospital services.

4.22.4 - Risk-Based Provider Payment: Necessary Factors for Protected Discounts

(Rev. 71, 04-09-04)

If the buyer is a health maintenance organization or a competitive medical plan acting in accordance with a risk contract or under another state health care program, it need not report the discount, except as otherwise required under the risk contract.

4.23 - Hospital Incentives

(Rev. 71, 04-09-04)

As many hospitals have become more aggressive in their attempts to recruit and retain physicians and increase patient referrals, physician incentives (sometimes referred to as “practice enhancements”) are becoming increasingly common. Some physicians actively solicit such incentives. These incentives may result in reductions in the physician's professional expenses or an increase in their revenues. In exchange, the physician is aware that he or she is often expected to refer the majority, if not all, of his or her patients to the hospital providing the incentives.

The OIG has become aware of a variety of hospital incentive programs used to compensate physicians (directly or indirectly) for referring patients to the hospital. These arrangements are prohibited by the anti-kickback statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid.

These incentive programs can interfere with the physician's judgment of what is the most appropriate care for a patient. They can inflate costs to the Medicare program by causing physicians to inappropriately overuse the services of a particular hospital. The incentives

may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute care facility) offering the best or most appropriate care for that patient. Indicators of potentially unlawful activity include:

- Payment of any sort by the hospital each time a physician refers a patient to the hospital.
- The use of free or significantly discounted office space or equipment (in facilities usually located close to the hospital).
- Provision of free or significantly discounted billing, nursing, or other staff services.
- Free training for a physician's office staff in areas such as management techniques, CPT coding, and laboratory techniques.
- Guarantees which provide that, if the physician's income fails to reach a predetermined level, the hospital supplements the remainder up to a certain amount.
- Low-interest or interest-free loans, or loans that may be “forgiven” if a physician refers patients (or some number of patients) to the hospital.
- Payment of the cost of a physician's travel and expenses for conferences.
- Payment for a physician's continuing education courses.
- Coverage on hospital's group health insurance plans at an inappropriately low cost to the physician.
- Payment for services (which may include consultations at the hospital) that require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of services furnished.

When PSCs and Medicare contractor BI units learn of a questionable hospital incentive program, the matter shall be referred to OIG/OI.

The PSCs and Medicare contractor BI units shall not provide, in writing or orally, an opinion on whether or not a particular business arrangement is in violation of the kickback law.

4.24 - Breaches of Assignment Agreement by Physician or Other Supplier

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

A. Criminal Penalty

The law provides that any person who accepts an assignment of benefits under Medicare, and who “knowingly, willfully, and repeatedly” violates the assignment agreement, shall be guilty of a misdemeanor and subject to a fine of not more than \$2,000, or imprisonment of not more than 6 months, or both.

B. Administrative Sanction

The CMS may revoke the right of a physician (or other supplier, or the qualified reassignee of a physician or other supplier) to receive assigned benefits, if the physician (or other party) who has been notified of the impropriety of the practice:

- Collects or attempts to collect more than the Medicare-allowed charge as determined for covered services after accepting assignment of benefits for such items or services, or
- Fails to stop collection efforts already begun or to refund monies incorrectly collected.

C. Civil Monetary Penalties (CMPs)

The statute provides for CMPs of up to \$2,000 per item or service claimed against any person who violates an assignment agreement.

D. Action by ACs or Medicare Contractors on Receipt of Initial Complaint

Upon receipt of the initial assignment agreement violation complaint or complaints against a physician, ACs and Medicare contractors shall develop the facts to ascertain whether the allegation is valid, regardless of whether the complaint is referred from an SSA FO, an OIFO, a beneficiary, or the RO.

If a violation has occurred, the AC or Medicare contractor shall contact the physician in person, by phone, or by mail to explain the obligations assumed in accepting assignment and to obtain his/her assurance that improperly collected monies are being refunded and that further billings in violation of the assignment agreement will cease. The AC or Medicare contractor shall inform the physician of the possible criminal penalty discussed in subsection A (above), the possible administrative sanction (i.e., revocation of the assignment privilege) discussed in subsection B, and the possible CMPs discussed in subsection C. The dates and other particulars of the contact with the physician shall be recorded.

The AC or Medicare contractor shall supplement any personal or phone contact with a letter to the physician explaining his/her assignment obligations and the possible

sanctions. The AC or Medicare contractor shall close the case with that letter if the physician response is satisfactory.

A satisfactory response shall include, at a minimum, the following:

- The physician acknowledges the obligations of the assignment agreement and agrees:
 - To make any necessary refund
 - To credit the refund due against other amounts owed, and
 - To stop further incorrect billing and to refund or credit any amount due the complainant as verified by the AC or Medicare contractor.

If the physician response is unsatisfactory, the AC or Medicare contractor shall refer the case to the PSC or the Medicare contractor BI unit for further action. The action taken by the PSC or Medicare contractor BI unit depends on the circumstances. If the physician persists in billing the patient for the charges that gave rise to the complaint or fails to make any refund due, the PSC or Medicare contractor BI unit shall develop (including completion of the SSA-2808, if received) (see PIM Chapter 4, §4.24H) and refer the case to the RO for initiation of steps to revoke the physician's assignment privilege. However, the RO may find it desirable to give the physician further written warning before undertaking such action.

If the physician, after having been warned, has violated his/her assignment agreement in connection with additional claims, see subsection E, below.

E. Action by Program Safeguard Contractor or Medicare Contractor Benefit Integrity Unit When Violations Occur After Warning

Upon receipt of a new assignment violation complaint(s) after a physician has been given the warning described in subsection D, the PSC or Medicare contractor BI unit shall develop the facts and shall refer the case to the RO with a report, regardless of whether the complaint is referred from an SSA FO, OIFO, or RO. PSCs or Medicare contractor BI units may wish to substitute an oral report to the RO in situations where the PSC or Medicare contractor BI unit has resolved the repeat violation. The RO considers whether to initiate action to revoke the physician's assignment privilege.

F. Procedure for Revoking Assignment Privilege

The RO may revoke assignment privileges when prosecution is inappropriate or not feasible. The RO notifies the physician of the proposed revocation of his right to receive assigned benefits and gives him/her 15 days to submit a statement, including any pertinent evidence, explaining why his/her right to payment should not be revoked. After the statement is received, or the 15-day period expires without the filing of the statement,

the RO determines whether to revoke the physician's right to receive payment. If the determination is to revoke the physician's right to receive payment, the RO notifies the AC or Medicare contractor to suspend payment on all assigned claims received after the effective date of the revocation. The RO also notifies the physician of the revocation, and of his/her right to request a formal hearing on the revocation within 60 days. (The RO may extend the period for requesting a hearing.)

If the physician requests a formal hearing (to be conducted by a member of the Hearing Staff of the Office of Budget and Administration, CMS) and the hearing officer reverses the revocation determination, the RO instructs the AC or Medicare contractor to pay the physician's claims.

If the hearing officer upholds the revocation determination, or if no request for a hearing is filed during the period allowed, the RO instructs the AC or Medicare contractor to make any payments otherwise due the physician to the beneficiary who received the services or to another person or organization authorized under the law and regulations to receive the payments. (See the IOM, Claims Processing Manual, Pub. 100-04, chapter 1, §30.2 for payment to a representative payee or legal representative.) If the beneficiary is deceased, ACs or Medicare contractors shall make payment in accordance with the requirements of the IOM, Claims Processing Manual, Pub. 100-04, chapter 1, §§30.2.15, 50.1.3-50.1.6 to the person who paid the claim, to the legal representative of the beneficiary's estate, or to his/her survivors. (ACs or Medicare contractors shall not make payment to the physician.) The revocation remains in effect until the RO finds that the reason for the revocation has been removed and there is reasonable assurance that it will not recur. The RO's decision to continue the revocation is not appealable.

When the right of a person or organization to receive assigned payment is revoked, the revocation applies to any benefits payable to that person or organization throughout the country. The RO is responsible for notifying those ACs or Medicare contractors who are likely to receive claims.

See IOM, Pub. 100-04, chapter 1, §§30.2-30.2.8.3 for the effect of revocation of a physician's or other person's assignment privileges on the right of a hospital or other entity to accept assignment for his/her services. This section also contains information concerning the effect of revocation of a hospital's or other entity's assignment privileges on the right of a physician or other person for whom it has been billing to bill for his/her own services.

G. Other Considerations

Because of the government's responsibility to prosecute persons who repeatedly violate the assignment agreement, effective monitoring of such offenses is very important. The factors involved in each case may vary, and PSCs and Medicare contractor BI units shall discuss with the RO, OIFO as appropriate, any situation where the PSCs and Medicare contractor BI units believe that legal or administrative action is necessary. In addition, PSCs and Medicare contractor BI units shall utilize the specific control measures and

referral procedures in accordance with RO/OIG-OI direction. The RO may review the AC's or Medicare contractor's actions to assure that assignment violations are being properly tracked and reported.

The ACs and Medicare contractors shall notify physicians and other suppliers of the implications of §1842(b)(3)(ii) of the Act, since the penalties for violations of the assignment agreement are significant. ACs and Medicare contractors shall use the language contained in these letters, or similar language, when contacting providers regarding assignment violation. ACs and Medicare contractors shall ensure that all physicians are made aware of the penalties that can be imposed. This deters assignment violations and works against a defense by physicians that they had no knowledge of these laws.

H. Form for Reporting Assignment Agreement Violations

Form SSA-2808, Notice of Reported Assignment Agreement Violation, is specifically designed for SSA FOs and ACs and Medicare contractors to use in handling assignment agreement violations. SSA FOs use this form for referral and control of complaints. ACs and Medicare contractors use it to report action on complaints.

SSA FOs are responsible for completing sections one and two completely and clearly. They are to forward the original plus one copy and a second copy is to be sent to the servicing RO. A third copy is kept by the SSA FO for control and follow-up purposes. A fourth copy is sent to the appropriate RO for informational purposes.

In the event that there is an undue delay (in excess of 45 days) by the AC or Medicare contractor in processing complaints, the SSA FO sends periodic interim reports (monthly) to beneficiaries/complainants informing them that as soon as action is taken, notification will be sent to them. This action precludes excessive inquiries to the AC or Medicare contractor. If an SSA FO wishes to determine the status of the complaint, it contacts the RO.

The ACs or Medicare contractors shall complete section 3 of the Form SSA-2808 and forward a copy to the RO when appropriate action is completed. The RO notifies the originating SSA FO of the action taken.

4.25 - Participation Agreement and Limiting Charge Violations (Rev. 71, 04-09-04)

Section 2306 of the Deficit Reduction Act of 1984 established a physician/supplier participation program. The Omnibus Budget Reconciliation Act of 1989 established a limitation on actual charges by non-participating physicians (see §1848(g) of the Act). Participating physicians/suppliers who violate their participation agreements, and non-participating physicians who knowingly, willfully, and repeatedly increase their charges to Medicare beneficiaries beyond the limits, are liable for action in the form of CMPs, assessments, and exclusion from the Medicare program for up to 5 years, or both.

Criminal penalties also apply to serious violations of the participation agreement provisions.

For further discussion of the participation agreement and limiting charge provisions, see Medicare Carriers Manual §§5000ff. and 7555, respectively.

4.26 – Supplier Proof of Delivery Documentation Requirements (Rev. 71, 04-09-04)

Suppliers are required to maintain proof of delivery documentation in their files. Documentation must be maintained in the supplier's files for 7 years.

Proof of delivery is required in order to verify that the beneficiary received the DMEPOS. Proof of delivery is one of the supplier standards as noted in 42 CFR, 424.57(12). Proof of delivery documentation must be made available to the DMERC upon request. For any services, which do not have proof of delivery from the supplier, such claimed items and services shall be denied and overpayments recovered. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG for investigation and/or imposition of sanctions.

4.26.1 - Proof of Delivery and Delivery Methods (Rev. 71, 04-09-04)

For the purpose of the delivery methods noted below, **designee** is defined as:

“Any person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary.”

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The relationship of the designee to the beneficiary should be noted on the delivery slip obtained by the supplier (i.e., spouse, neighbor, etc.). The signature of the designee should be legible. If the signature of the designee is not legible, the supplier/shipping service should note the name of the designee on the delivery slip.

Suppliers may deliver directly to the beneficiary or the designee. An example of proof of delivery to a beneficiary is having a signed delivery slip, and it is recommended that the delivery slip include: 1) The patient's name; 2) The quantity delivered; 3) A detailed description of the item being delivered; 4) The brand name; and 5) The serial number. The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply shall be the date of service on the claim.

If the supplier utilizes a shipping service or mail order, an example of proof of delivery would include the service's tracking slip, and the supplier's own shipping invoice. If possible, the supplier's records should also include the delivery service's package identification number for that package sent to the beneficiary. The shipping service's tracking slip should reference each individual package, the delivery address, the corresponding package identification number given by the shipping service, and if possible, the date delivered. If a supplier utilizes a shipping service or mail order, suppliers shall use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a form of proof of delivery. The descriptive information concerning the DMEPOS item (i.e., the patient's name, the quantity, detailed description, brand name, and serial number) as well as the required signatures from either the beneficiary or the beneficiary's designee should be included on this invoice as well.

For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill. This shall be done to ensure that the refilled item is necessary and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DMERCs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.

For those patients that are residents of a nursing facility, upon request from the DMERC, suppliers should obtain copies of the necessary documentation from the nursing facility to document proof of delivery or usage by the beneficiary (e.g., nurse's notes).

4.26.2 – Exceptions

(Rev. 83, Issued: 08-27-04, Effective: 09-27-04, Implementation: 09-27-04)

Exceptions to the preceding statements concerning the date(s) of service on the claim occur when the items are provided in anticipation of discharge from a hospital or nursing facility. A supplier may deliver a DMEPOS item to a patient in a hospital or nursing facility for the purpose of fitting or training the patient in the proper use of the item. This may be done up to 2 days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (Patient's Home). The item must be for subsequent use in the patient's home. No billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility.

A supplier may not bill for drugs or other DMEPOS items used by the patient prior to the patient's discharge from the hospital or a Medicare Part A nursing facility stay. Billing the DMERC for surgical dressings, urological supplies, or ostomy supplies that are provided in the hospital or during a Medicare Part A nursing facility stay is not allowed.

These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the patient from the hospital or nursing facility. Any attempt by the supplier and/or facility to substitute an item that is payable to the supplier for an item that, under statute, should be provided by the facility, may be considered to be fraudulent. These statements apply to durable medical equipment delivered to a patient in hospitals, skilled nursing facilities (Place of Service = 31), or nursing facilities providing skilled services (Place of Service = 32).

A supplier may deliver a DMEPOS item to a patient's home in anticipation of a discharge from a hospital or nursing facility. The supplier may arrange for actual delivery of the item approximately 2 days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (Patient's Home).

4.27 - Annual Deceased-Beneficiary Postpayment Review **(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)**

The PSCs and Medicare contractor BI units shall identify and initiate actions to recover payments with a billed date of service that is after the beneficiary's date of death. The identification of improperly paid claims shall be performed at a minimum on an annual fiscal year basis for beneficiaries who died the previous fiscal year. In addition, the PSCs shall forward the identified overpayments to the AC for recoupment. The associated overpayment recoupment shall be initiated as soon as administratively possible.

EXAMPLE: Services rendered to beneficiaries who died during fiscal year 2002 - PSCs and Medicare contractor BI units must identify improperly paid services. Upon identification, PSCs and Medicare contractors will refer this information to their respective AC or appropriate area within the Medicare contractor for recoupment. ACs and Medicare contractors must issue associated overpayment demand letters as soon as administratively possible.

The PSCs, ACs, and Medicare contractors are not required to perform medical review for paid claims with dates of service after a beneficiary's date of death. PSCs and Medicare contractor BI units shall identify the service that has been rendered after the beneficiary's date of death, and refer it to their respective AC or appropriate area within the Medicare contractor. Subsequent notification to the provider that an improper payment has been made, for which recovery is being sought, shall be initiated by the AC or the Medicare contractor.

At a minimum, PSCs and Medicare contractor BI units shall identify deceased beneficiaries and associated improperly paid claims by using one of the following two options:

- Utilize Internal Beneficiary Eligibility Records - This option involves performing a data extract against eligibility files for all beneficiaries within the PSC's or Medicare contractor BI unit's jurisdiction and identifying those beneficiaries who

have died during the applicable fiscal year. Once the list of deceased beneficiaries has been identified, PSCs and Medicare contractor BI units utilize the claims processing history files to identify any services/claims containing a paid date of service that is after the CWF-posted date of death.

- Utilize External Beneficiary Eligibility Records - This option allows PSCs and Medicare contractor BI units to utilize a CMS-created annual computer file of all deceased beneficiaries. On an annual calendar year basis, CMS creates computer files of all Medicare beneficiaries who died in the preceding 2 calendar years. These computer files should be available for PSCs and Medicare contractor BI units to download from the Data Center by mid-February of each year. PSCs and Medicare contractor BI units then review the format for this file to determine if any changes have been made from the previous fiscal year file. There have been known instances where a beneficiary's date of death is reported in both calendar year files. If such a situation is determined, the PSC or Medicare contractor BI unit shall use the latest calendar year file as the date of death. In accordance with the Health Insurance Portability and Accountability Act of 1996, a security firewall has been installed to protect the privacy rights of deceased beneficiaries. This firewall prevents unauthorized users from gaining access to the files of deceased beneficiaries. Due to the confidential information within these files, PSCs and Medicare contractor BI units will not be able to access them without their secured authorized identification code being included in the CMS-allowed-access list associated with the files.

To have access to these files, the PSC and Medicare contractor BI unit shall submit the name of the person(s) who will be accessing the files, their CMS mainframe user identification number, the PSC or Medicare contractor name and contractor number, the PSC Task Order number, and a telephone number. Only the person(s) identified will be allowed access to the files. Submit this information via e-mail to the CO Director of the Division of Benefit Integrity Management Operations.

The annual computer files are located on CMS's mainframe computer and may be found using the dataset naming convention "c@pig.#dbpc.deceased.benes.dodyyyy", where "yyyy" is equal to the calendar year in which the beneficiaries died. The format for this file is a text file and may also be found using "c@pig.#dbpc.deceased.benes.format". For example, computer file "c@pig.#dbpc.deceased.benes.dod2001" contains information on all Medicare beneficiaries who died during calendar year 2001. Computer file "c@pig.#dbpc.deceased.benes.dod.2002" contains information on all Medicare beneficiaries who died during calendar year 2002. Download both computer files and manipulate the data to determine those beneficiaries who died during fiscal year 2002 (October 1, 2001 - September 30, 2002). Then utilize the claims processing history files to identify any services/claims containing a paid date of service that is after the posted date of death.

The PSCs and Medicare contractor BI units may consider conducting analyses to determine if healthcare providers continue to bill inappropriately after the results of this

review have been completed (i.e., overpayments have been demanded and education regarding inappropriate billings have taken place). The PSCs and Medicare contractor BI units may consider developing an investigation on providers whose pattern of billings remains noncompliant.

On an annual basis, PSCs and Medicare contractor BI units shall submit a report on the accounting of the improper payments identified by the PSC or Medicare contractor BI unit and respective overpayments recouped by the AC and Medicare contractor. This report shall be due on December 5th of each year and sent to the Primary GTL. The report shall also be sent via e-mail to the CO Director of the Division of Benefit Integrity Management Operations.

4.28 - Joint Operating Agreement (Rev. 71, 04-09-04)

A Joint Operating Agreement (JOA) is a document developed by the PSC and the AC that delineates the roles and responsibilities for each entity specific to a Task Order.

As it applies to the PSC's task order, the JOA shall, at a minimum:

- Include a description and documentation of process/workflows that illustrate how the PSC and AC intend to interact with one another to complete each of the tasks outlined in the Task Order on a daily basis.
- Establish responsibility for who shall request medical records/documentation(s) not submitted with the claim.
- Ensure that the AC communicates to the PSC any interaction with law enforcement on requests for cost report information.
- Establish responsibility for how medical documentation that has been submitted without being requested shall be stored and tracked.
- Establish responsibility for how medical documentation that has been submitted without being requested shall be provided to the PSC if documentation becomes necessary in the review process.
- Mitigate risk of duplicate medical documentation requests.
- Ensure that there is no duplication of effort by the PSC and the AC (e.g., the AC must not re-review PSC work).
- Identify the JOA participants
- Describe the roles and responsibilities of the PSC and the AC

- Clearly define dispute resolution processes
- Describe communication regarding CMS changes
- Include systems information
- Include training and education
- Include complaint screening and processing (including the immediate referral by the AC second-level screening staff of provider complaints and immediate advisements to the PSC)
- Include data analysis
- Include suspension of payment
- Include overpayments processing
- Include excluded providers
- Include voluntary refunds
- Include incentive Reward Programs
- Include appeals
- Include provider enrollment
- Include system edits and audits
- Include requests for information
- Include FOIA and Privacy Act responsibilities
- Include interaction with law enforcement
- Include fraud investigations
- Include prepayment reviews
- Include postpayment reviews
- Include Harkin Grantees
- Include OIG Hotline referrals

- Include Self-Disclosures
- Include consent settlements
- Include securing email information
- Include JOA workgroup meetings
- Contain other items identified by CMS, the PSC, and/or AC

4.29 - Medicare Contractor Benefit Integrity Unit Quarterly Status Report (Rev. 71, 04-09-04)

This section only applies to Medicare contractors who have not transitioned their BI work to a PSC.

The Medicare contractor BI unit shall document the activities it performs and reports them to CMS using the Contractor Reporting of Operational & Workload Data (CROWD) system. The BI unit shall maintain data on the following topics:

- Complaints (volume, source, processing time, disposition)
- Volume and kinds of referrals to OI
- Networking activities
- Types of fraud and abuse identified and corrective actions taken, including administrative action

4.30 – Quality Improvement (QI) Program Reporting (Rev. 71, 04-09-04)

This does not apply to PSCs.

Medicare contractor BI units shall assist in protecting the Medicare Trust Fund from those entities that would seek payment for items and services under false or fraudulent circumstances. This includes effectively developing potential fraud cases and referral of them to the Office of Inspector General (OIG) for determining if criminal and/or civil statutes have been violated.

In order to accomplish their responsibilities, CMS requires the Medicare contractor BI units to develop BI QI programs. The purpose of the QI program is to systematically improve the quality of the case referrals; enhance proactive approaches to identify potential fraud; and identify program vulnerabilities resulting from investigative activities. The QI plan shall be submitted each fiscal year to the RO 30 days before the beginning of the fiscal year. The content of the BI QI program shall:

1. Ensure decisions made are effective in preventing, detecting, and deterring potential fraud in the Medicare program;
2. Ensure standard operational procedures are in place and are adhered to and monitored;
3. Improve the case development actions and documentation standards;
4. Ensure the proper handling of complaints;
5. Increase the potential acceptance of OIG case referrals by submitting quality referrals;
6. Improve the working relationship with law enforcement through enhanced networking and training;
7. Improve proactive use of data analysis;
8. Improve the quality of cases referred to law enforcement through partnering. Partnering is an informal meeting with law enforcement to discuss case details prior to referral.
9. Improve communication and coordination efforts with partners (OIG, FBI, other carriers, intermediaries, PSCs, etc.);
10. Implement and maintain a cross-functional data analysis team in each site. It will consist of representation from each functional unit and meet monthly to share data, observations of questionable billing practice patterns, voluntary refund information, and other concerns;
11. Improve and increase program safeguard actions including payment suspensions, prepayment review and referral to medical review, as appropriate.
12. Ensure proper maintenance and updating of the FID;
13. Ensure the accuracy of medical review decisions made in support of BI. The accuracy of these medical review determinations in support of BI whether made by BI or MR staff shall be a component of the BI QI program.

(Utilizing this tool will increase the number of cases accepted by law enforcement and ensure the efficiency and effectiveness of the program.)

The Medicare contractor BI unit shall submit the results of the QI program to the RO on a quarterly basis. This report shall include the following information:

- The date QI was performed and by whom;
- The program weakness or vulnerability;
- Source of the program weakness/vulnerability;
- How the program weakness/vulnerability was detected;
- The PIM chapter(s) and section(s) or Program Memorandum (PM) supporting the identification of the program weakness/vulnerability;
- Actions taken to correct the program weakness/vulnerability;
- Actions taken to avoid the same program weakness/vulnerability from recurring;
- How the weakness/vulnerability is being monitored for compliance;
- The results of individual and unit error rate percentages of quality reviews; and
- A synopsis of management practices within the context of the QI program.

4.31 – Vulnerability Report

(Rev. 118, Issued: 08-12-05; Effective/Implementation: 09-12-05)

Program vulnerabilities can be identified through a variety of sources such as the Chief Financial Officer's Audit, Fraud Alerts, the General Accounting Office, the Office of Inspector General (OIG), and PSC and Medicare contractor operations, as examples. PSCs and Medicare contractor BI units shall submit any identified program vulnerabilities to RO and CO on a quarterly basis (i.e., 1/15, 4/15, 7/15, and 10/15). The identified vulnerabilities shall also include recommendations for resolving the vulnerability, any action taken to resolve the vulnerability, and shall describe the detection methodology.

The PSC and Medicare contractor BI unit shall send a copy of the identified vulnerabilities to the Primary GTL, Associate GTL, and RO. The PSC and Medicare contractor BI unit shall also send the CO a copy of the identified vulnerabilities to the following address: vulnerability@cms.hhs.gov